SONOST 2000

User's Manual

Model: SONOST-2000

Council Directive 93/42/EEC Concerning Medical Device

http://www.osteosys.com

OsteoSys Co., Ltd.

SONOST 2000

User's Manual

CAUTION !
1. **You must be well acquainted with this manual before using it.** 2. **This manual should be placed where the user could read it whenever necessary.**

Software Version : 2.01.01

Documentation Version : 012(2003.03.17)

Part Number : OT01-2R0422-02-MUL

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Thank you for purchasing SONOST-**2000** Ultrasound Bone Densitometer. To ensure safe operation and long-term performance stability, it is essential that you fully understand the functions and operating, maintenance instructions by reading this manual before operating the equipment.

Particular attention must be paid to all warnings, cautions and notes incorporated herein.

Incorrect operation, or failure of the user to maintain the equipment relieves the manufacturer or his agent of the system's noncompliance with specifications or of responsibility for any damage or injury.

The following conventions are used throughout the manual to denote information of special emphasis.

WARNING !
"Warning" is used to indicate the presence of hazard that can cause severe personal injury, death or substantial property damage if the warning is ignored.

CAUTION !
"Caution" is used to indicate the presence of hazard that will or can minor personal injury and property damage if the caution is ignored.

NOTE !
"Note" is used to notify the user of installation, operation or maintenance information that is important but not hazard related.

The symbols which are shown in this manual or SONOST-2000

The noticed information which should be concerned with explanation in this manual

The noticed information when the device is operated

The reference page or section

Applied Part Type B

I and O on power switch represent ON and OFF, respectively

The Attention symbol that marks warning and important information in the user's manual

The conductor provides a connection between equipment and the potential equalization bus-bar of the electrical installation

The date of manufacture

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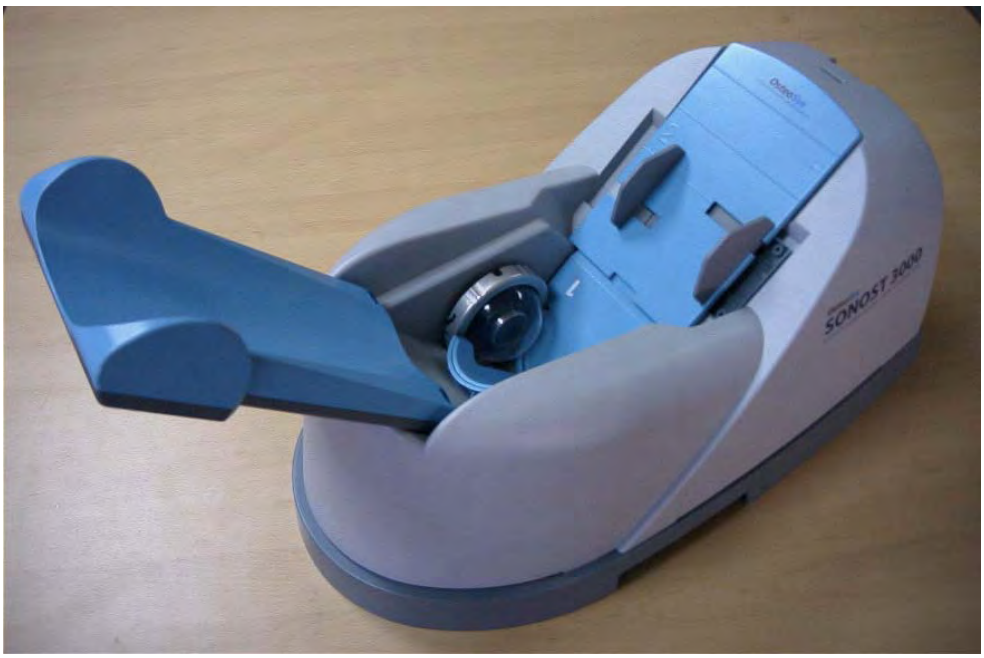
Chapter 1. Introduction



1.1 General Product Information

Osteoporosis is one of the serious diseases. This device is a bone densitometer which estimates a bone mineral density of the calcaneus by ultrasound.

It takes about 15 seconds to measure the density and to display the shape of ultrasonic wave by computing simulation on the monitor.

To ensure safe operation and long-term performance stability, it is essential that you fully understand the functions, operating and maintenance instructions reading this manual before operating the equipment.

Features and Cautions !

- This device is an ultrasound bone densitometer which has ±0.2(T-score) precision error.
- The equipment must be operated only by, or under supervision of a qualified person.
- When you give the appropriate commands in SONOST-2000 software, ultrasonic waves are generated. The generated ultrasonic waves pass through the Patient's calcaneus and the electric signal is treated by SONOST-2000 algorithm.
- SONOST-2000 measures speed of sound(SOS) and the frequency-dependent attenuation of the sound waves(BUA), and combines them to form a clinical measure called Bone Quality Index(BQI)
- All operators must understand the potential hazards in the use of medical electronic devices. They must be able to recognize hazards and protect themselves and others from injury.
- The system should be placed at least 20cm from the wall. However the USB cable length should not be longer than 3.0m.
- Never remove any system covers.
- If the fuses are gone, exchange the same type (250V T315AL). Otherwise a fire may occur or you may receive electric shock.
- In case of changing the PC or the printer for other products, check them according to IEC/EN60601-1-1.
- Unplug the power cord before you move or clean the device and after using SONOST-2000
- For installation and operation of this equipment national regulation shall be considered.

Chapter 2. Configuration of SONOST-2000

2.1 Composition of SONOST-2000

2.1.1 Shape and Components of SONOST-2000

2.1.2 Shape and Components of Measurement Equipment

2.1.3 Keyboard

2.1.4 Accessories List

2.1.5 Articles List

2.2 Installation of SONOST-2000

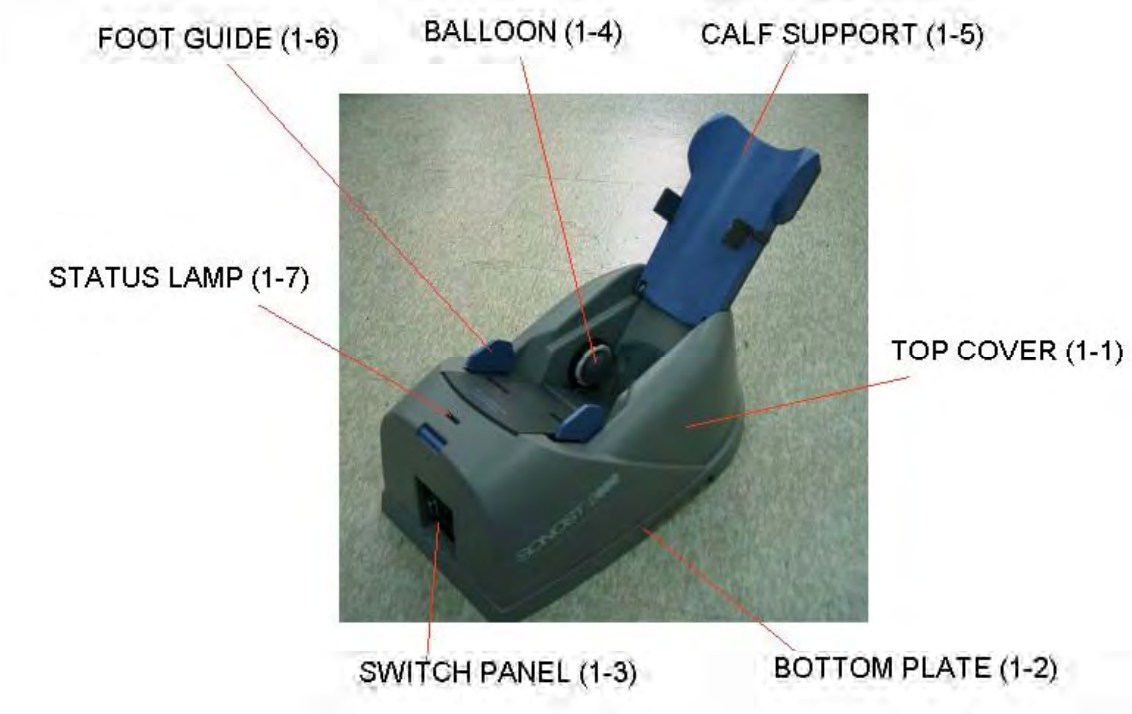
2.3 Before Turning on Power

2.1 Composition of SONOST-2000

2.1.1 Shape and Components of SONOST-2000

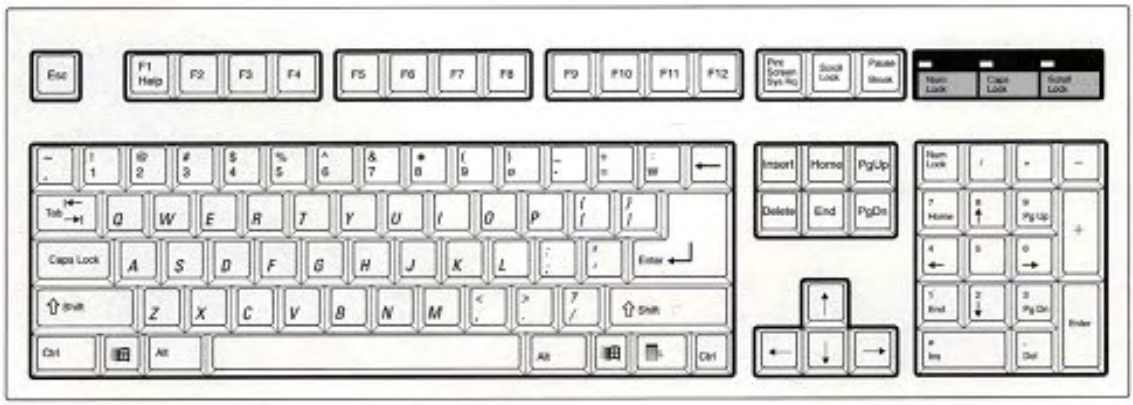
< Front View >

2.1.2 Shape and Components of Measurement Equipment



NO	Name	Function
1-1	TOP COVER	Protection for internal circuit
1-2	BOTTOM PLATE	Fixation for device position & top cover
1-3	SWITCH PANEL	Switch, Power cord, RS-232 Connector
1-4	BALLOON	Connect between heel and ultrasound probe
1-5	CALF SUPPORT	Leg fixation for diagnosing
1-6	FOOT GUIDE	Foot fixation for diagnosing
1-7	STATUS LAMP	Present status of the Device

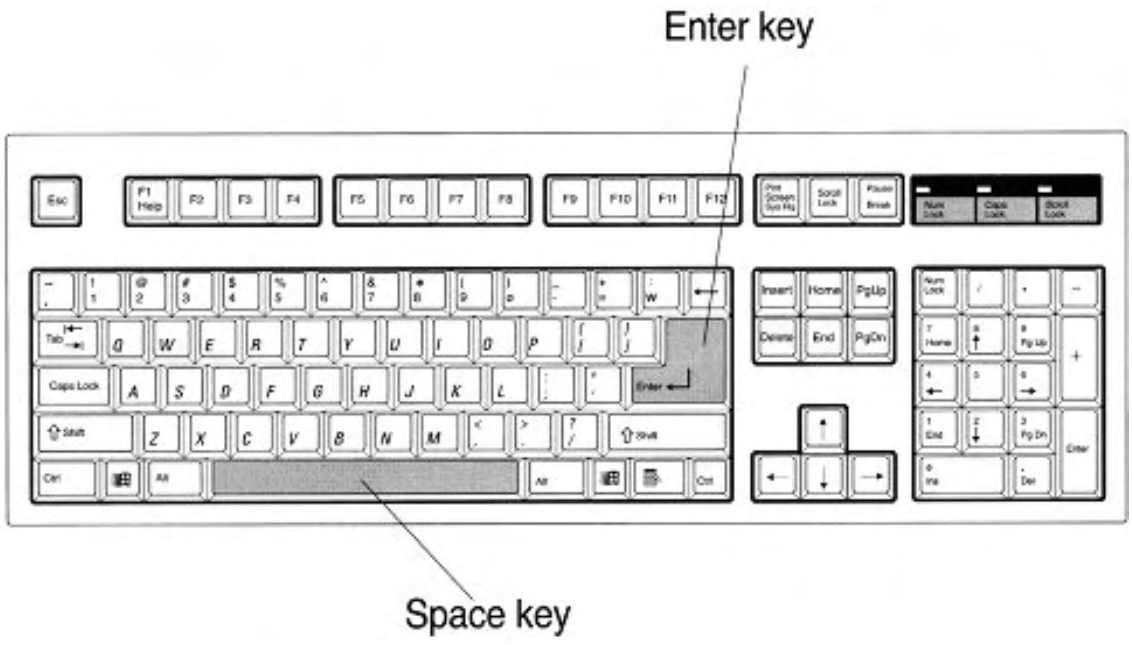
2.1.3 Keyboard



Keyboard

Activate SONOST-2000 by pressing a key on the keyboard according to the instructions shown on the monitor.

The manual shows keys required to activate SONOST-2000 as shown below.



2.1.4 Accessories List

Check the following accessories before installing the system.
If they are not in good condition, contact to OsteoSys or its authorized dealer for this service.

Names of Products	Number	Uses
User's Manual	1	Make sure to keep it at a designated place so that users can read it anytime they need to
Foot Positioner	3	Use them in accordance with patients' foot size.
QC Phantom	1	It is used to calibrate the system. Keep it in the specified place and protect it against deformation by heat or pressure.
Injector	1	It helps to take water into the balloon easily.
Guide	5	It helps to take water into the balloon easily.
Device Cover	1	It prevents dust from gathering the inside of the device.
USB Cable	1	It is used to connect to the computer with the main body of SONOST-2000
Power Cable	1	It is used to connect to the source of electric power with the main body of SONOST-2000 Make sure to connect it with a grounded electric outlet.
Program CD	1	It is used to install the program on the computer.(The program is installed on the computer before being delivered)

2.1.5 Articles List

Check the following accessories before installing the system.
If they are not in good condition, contact to OsteoSys or its authorized dealer for this service.

2 Stockpiles and Replacement of Articles

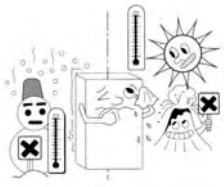
Names of Products	Number	Uses
Balloon / Housing	Balloon : 10 Housing : 3	It connects a foot with the ultrasound probes and helps ultrasound to progress between them. Keep the spare balloons and housings in a cool place.
Ultrasound Gel	2 bottles	It helps ultrasound to progress between a balloon and patient's heel
Alcohol	1 box	It removes some material which prevents ultrasound from progressing.
Ink Cartridge	Black : 1 unit Color : 1 unit	Spec. : HP 3820

2.2 Installation of SONOST-2000

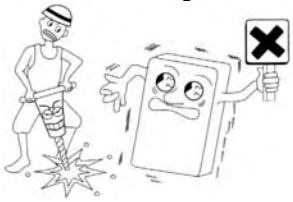
NOTE !
Since SONOST-2000 is made up of precise components, you should install the product according to instructions below.

Do not install and keep SONOST-2000 at excessively high or low temperatures.

Proper temperature: 18~27

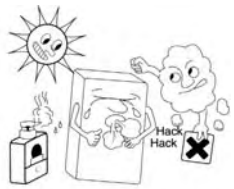


Do not install or keep SONOST-2000 in the place where the machine can be rocked or shaken. Make sure to place the system parallel to the floor.



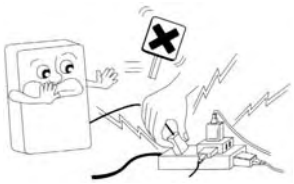
Do not install the system in the place with polluted air and high humidity and do not expose the machine to direct ray sunlight. It is advisable to use SONOST-2000 in the place equipped with air conditioning or heating.

Proper humidity: 20~80%

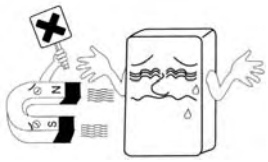


Install SONOST-2000 in the place where it is free from water or chemicals.

Do not share the power outlet with other products through an extension cord.

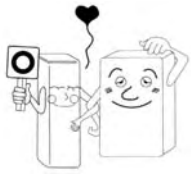


Do not use the system near equipment that generates strong magnetic fields.



Do not cover ventilation of the system or place it near the wall. High inside temperature of the machine might cause a fire.

100-240V is usable. When SONOST-2000 is taken out of a warehouse, insulating transformers should be set to 100-240V. Since sudden power outage can remove all data saved in the product, you should install SONOST-2000 in the place where a power supply is stabilized.



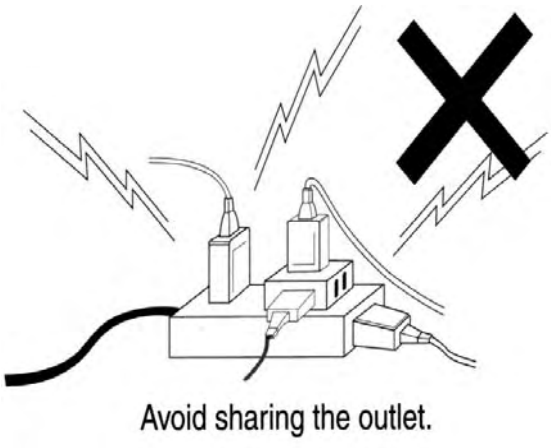
2.3 Before Turning on Power

(1) Connection of Power & USB Cable(with the device)

Plug in the cable.

Plug into the connector.
When you detach the cable from the main body of SONOST-2000, do not hold the cable and instead hold the connector. Otherwise the wire could be down.

(2) Connection of Power Cable(with the outlet)



CAUTION !

- Make sure that the covering of cable is not damaged to prevent electric shock or short circuit.
- If you find any damage or any sign of it, immediately contact an agency.
- Put the Power cord into only one plug
- Make sure not to share the power outlet to prevent SONOST-2000 from being affected.

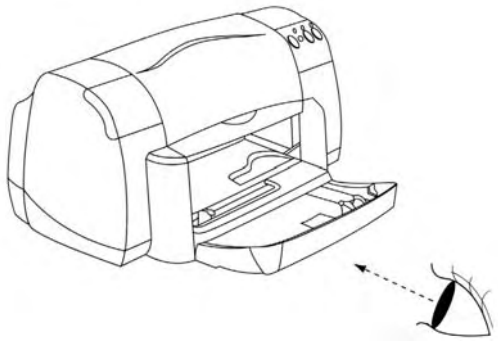
(3) Adjust the balloons in the device.

4.2.2 Stockpile and Replacement of Articles

(4) Make sure that paper is properly provided to the printer.

Supply of paper

4.2.2 Stockpile and Replacement of Articles



Chapter 3. Using SONOST-2000

3.1 Using H/W

3.1.1 Applying the Balloon to the Measuring Device

3.1.2 Using the QC Phantom

3.1.3 Patient Measurement Procedure

3.1.4 Disposing water

3.1.5 Where and how much apply to the Patient's heel

3.1.6 Correct position for Patient's foot & body

3.1.7 How to apply #1 & #2 foot positioner according to the Different foot sized patient.

3.2 Using S/W

3.2.1 Progress Table of Program

3.2.2 Using Program

3.2.2.1 Execution of Program and Configuration of the Incipient Environment

3.2.2.2 Registration & Deletion of Users

3.2.2.3 BQI Measurement

3.2.2.4 Revision & Deletion of Patient's Information

3.2.2.5 Inquiry & Deletion Clinical History of Existing Patients

3.2.2.6 Calibration of SONOST-2000

3.2.2.7 Data Backup

3.2.2.8 Configuration of Environment

3.2.2.9 Inactivation of SONOST-2000

3.1 Using H/W

3.1.1 Applying the Balloon to the Measuring Device

Clean the surface of the probe with an alcohol pad.

Attach the balloon to the probe holder.

Adjust the balloon housing to the probe holder.

Take water into the balloon using an injector until it is full(65~70cc).

Close it with the stopper.

Tap the balloon to remove bubbles inside of the balloon.

3.1.2 Using the QC phantom

3.2.2.6 Calibration of SONOST-2000

Insert the standard block positioner.

Apply gel on the both side of the QC Phantom.

Put the QC Phantom between the balloons.

3.1.3 Patient Measurement Procedure

Put the foot positioner in accordance with patient's foot size

- Ex) Using the #1foot positioner

- Ex) Using the #2 foot positioner

If you use the #2 foot positioner, necessarily, put it on the #1 foot positioner.

Complete feature.

Clean the both side of patient's heel with an alcohol pad.

Apply plenty of gel on the both side of patient's heel.

Insert patient's foot

Let a patient move his foot up and down for the balloons to be covered with ultrasound gel sufficiently.

Complete feature

Completer feature

Start to measure after adhering patient's calf to the calf supporter.

3.1.4 Disposing water

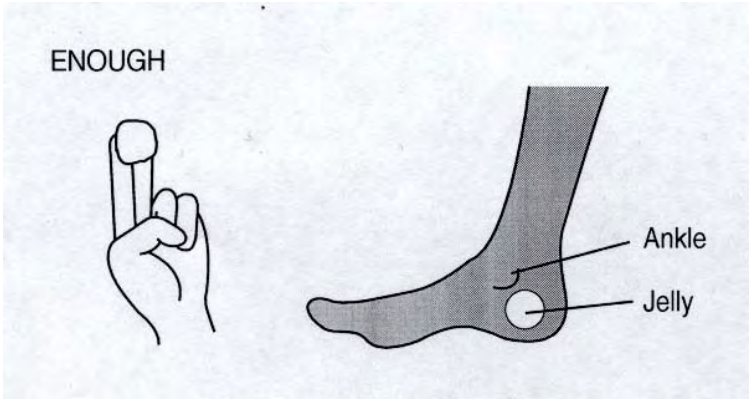
Dispose water inside the measurement device

Replacement period : 1 ~ 3(week)
If there is air in the balloons, fill up water promptly. Otherwise it causes an error when you measure patients' BMD.

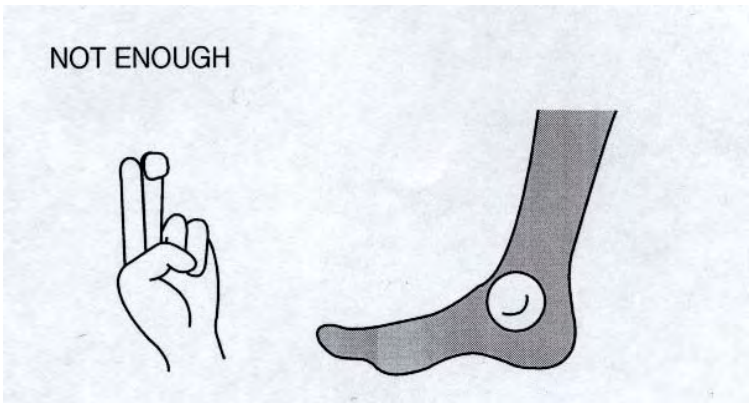
3.1.5 Where and how much apply to the Patient's heel

Before measuring, using alcohol to rub patient's heel : protection for removing air bubbles surface of patient's skin and other infections.

Apply plenty of ultrasound gel to both side of patient's heel



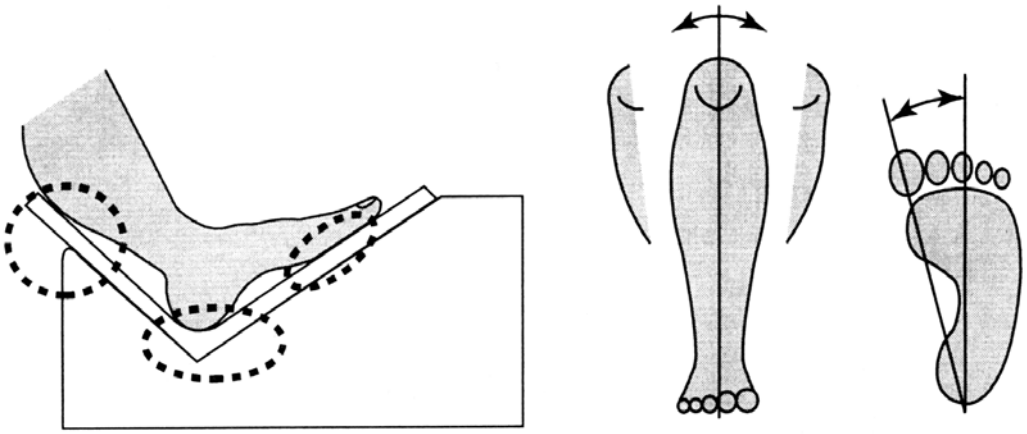
Good



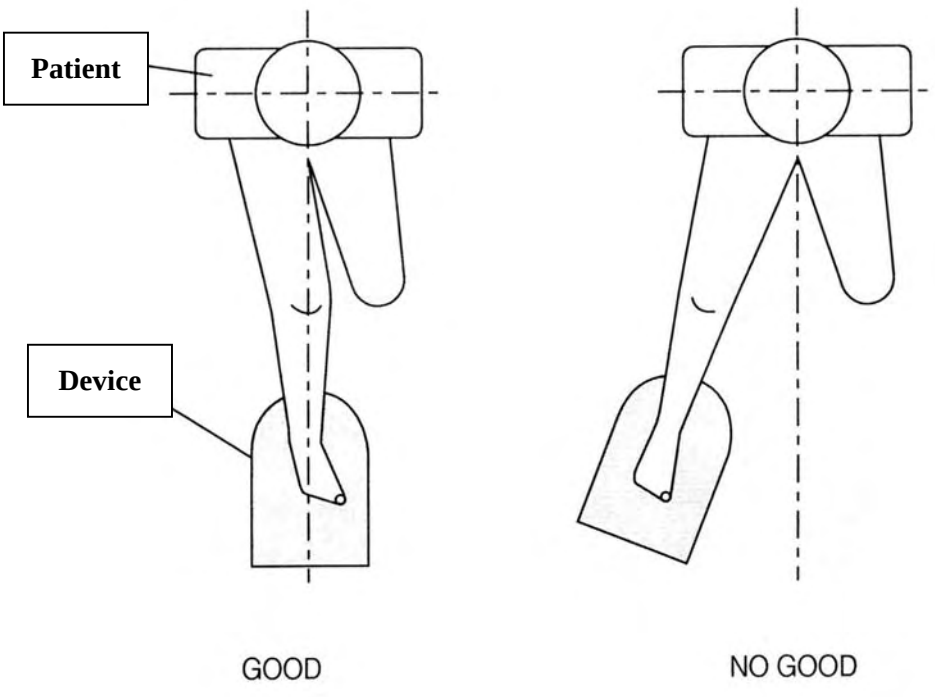
No Good

3.1.6 Correct position for Patient's foot & body

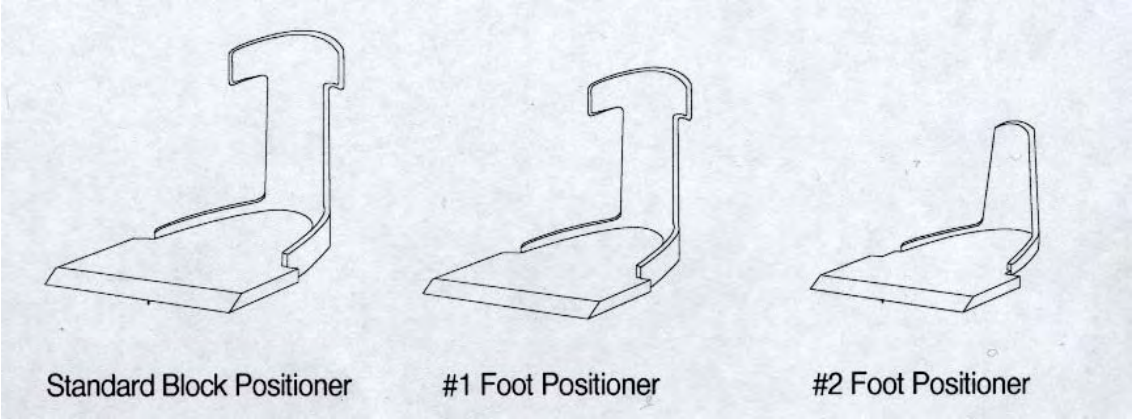
Adhere a heel to the measuring device closely as shown below.



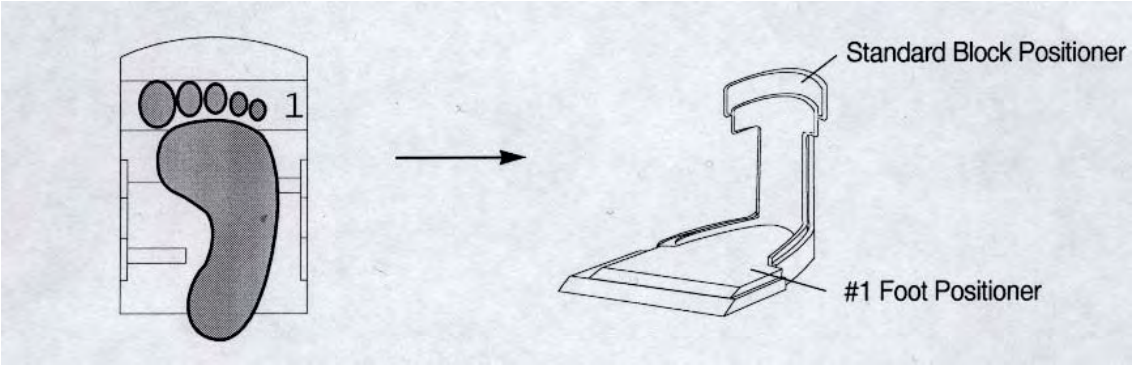
Make sure measuring device and body should be one line as shown below.



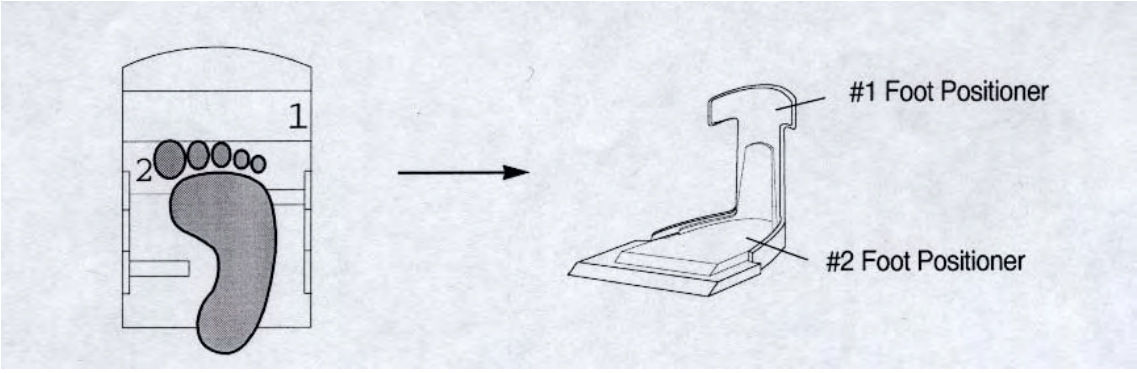
3.1.7 How to apply #1 & #2 foot positioner according to the Different foot sized patient



(1) In case patient's toes placed the #1 foot positioner, using the #1 foot positioner.



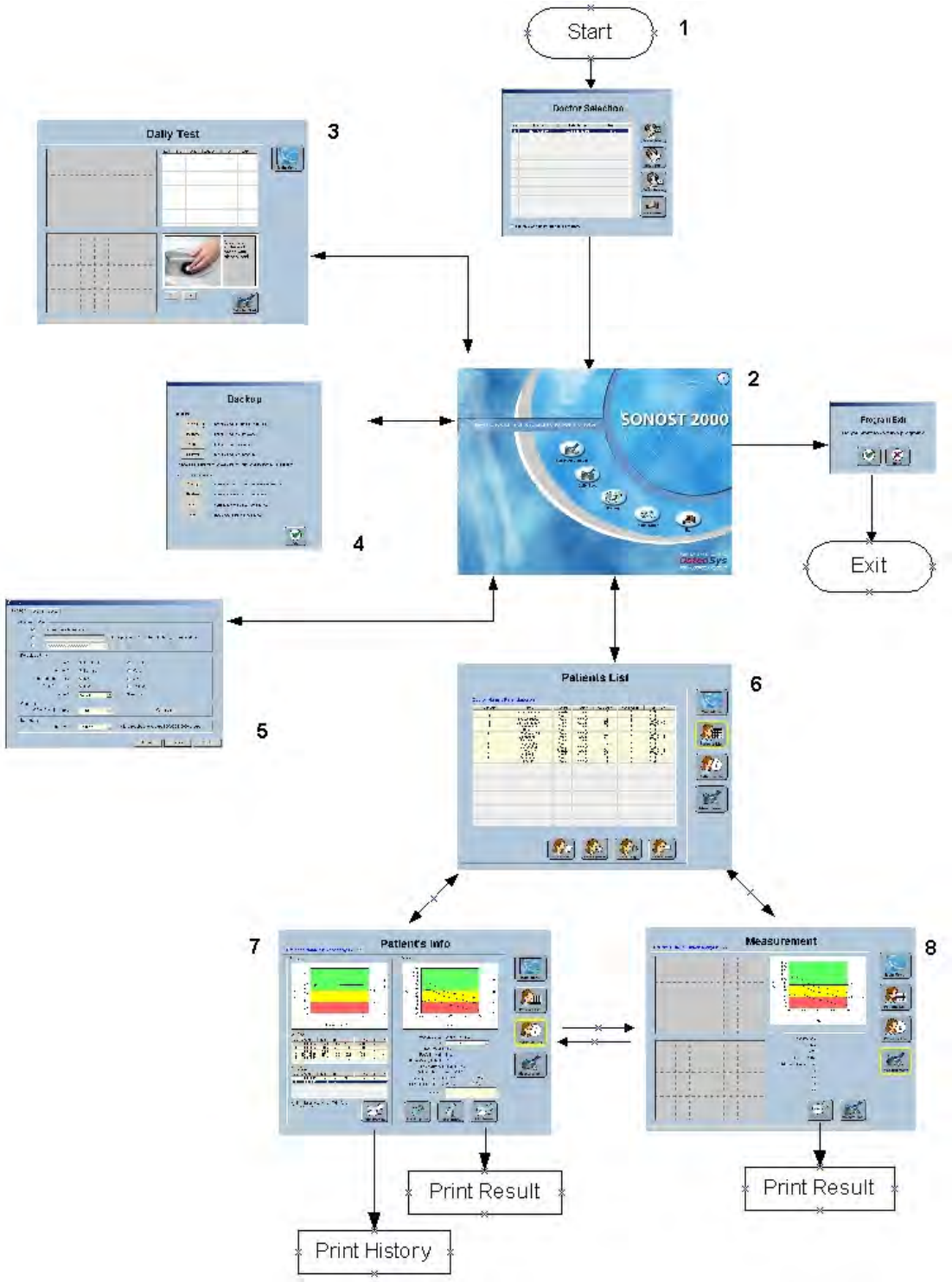
(2) In case patient's toes placed #2 foot positioner, using the #2 foot positioner.



NOTE !
Please make sure the #2 foot positioner should be placed on the #1 foot positioner.

3.2 Using S/W

3.2.1 Progress Table of Program



3.2.2 Using Program

3.2.2.1 Execution of Program and Configuration of the Incipient Environment

CAUTION !
If you hear any strange noise from the screen, switch it off and contact to OsteoSys or its Authorized dealer.

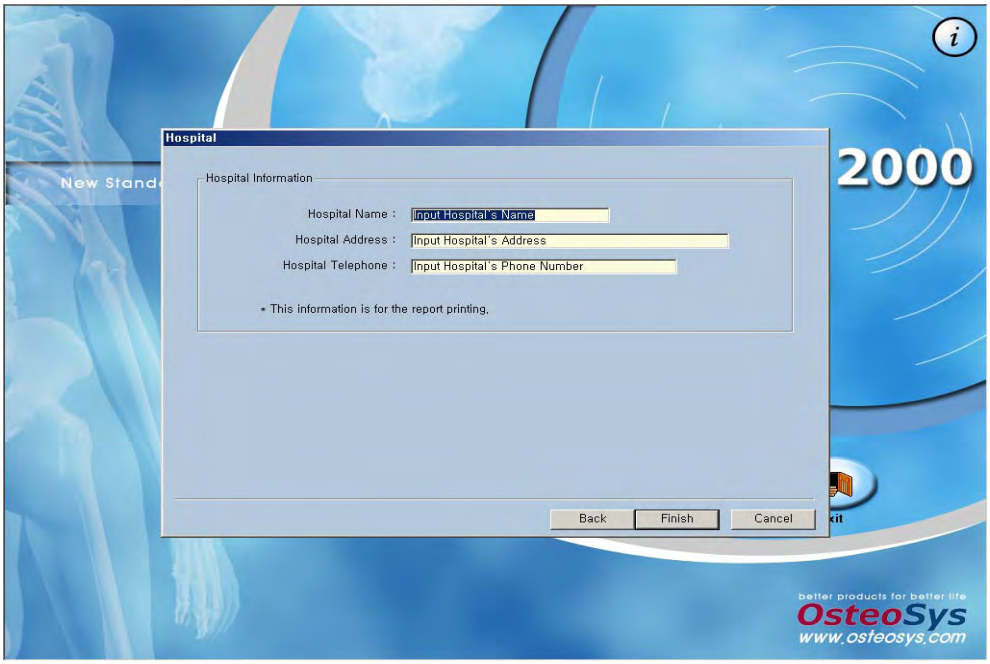
(1) Turn on the power switch.

(2) 10 seconds after calibration that checks functions of the system and memory device, the program is automatically activated and you should configure the incipient environment.

(3) Settings :

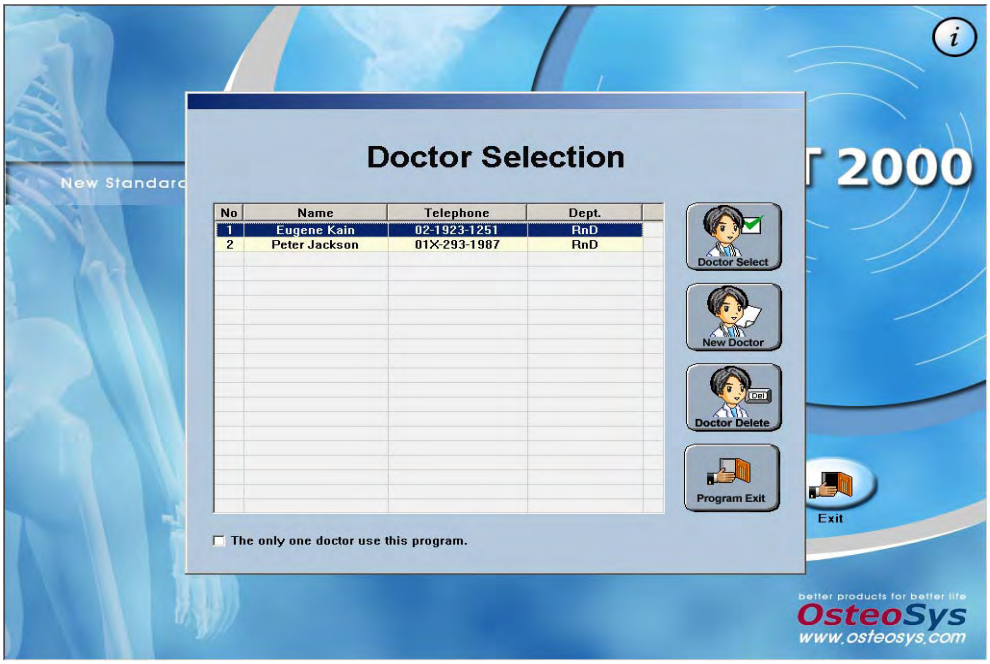
- Patient ID Mask : Set the type of patients' ID.
- Default Settings : Set the default measurement site, Patients' gender, menopause state, ethnicity, the function "Print Preview", etc.
- Language : Select your own language to use the program.

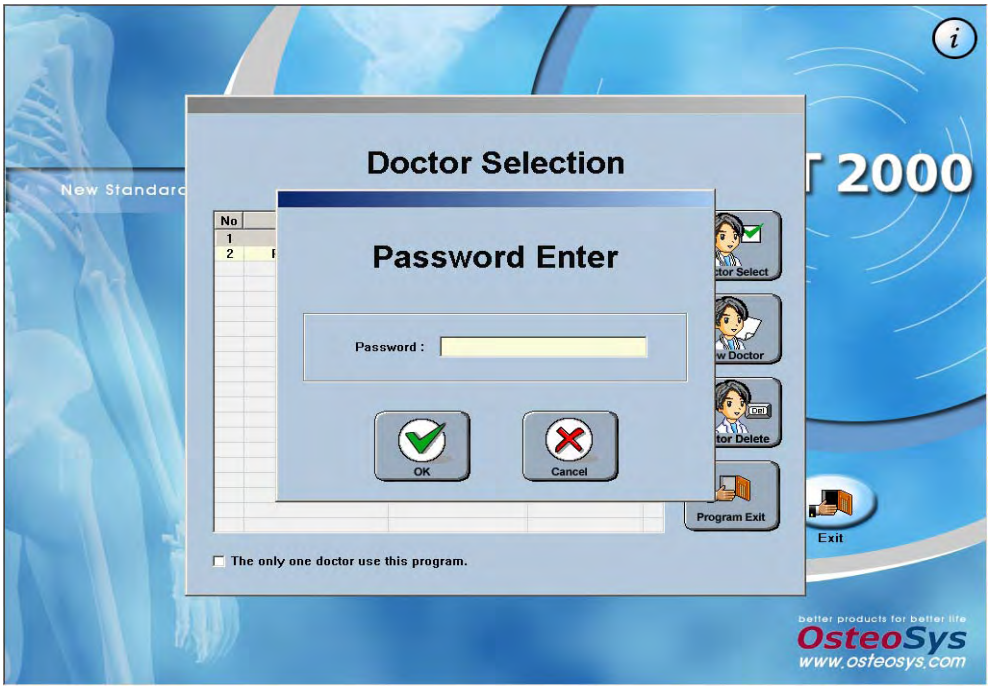
(4) Hospital : Set the name, address and phone number of your hospital.



3.2.2.2 Registration & Deletion of Users

(1) As soon as you configure the user environment, the "Doctor Selection" window appears as shown below. If you are a registered user(doctor), click the "Doctor Select" button after selecting your name in the "Doctor Selection" window using the mouse. And then if you enter the password in the edit box "Password Enter" and click the "OK" button, you can log in the program.





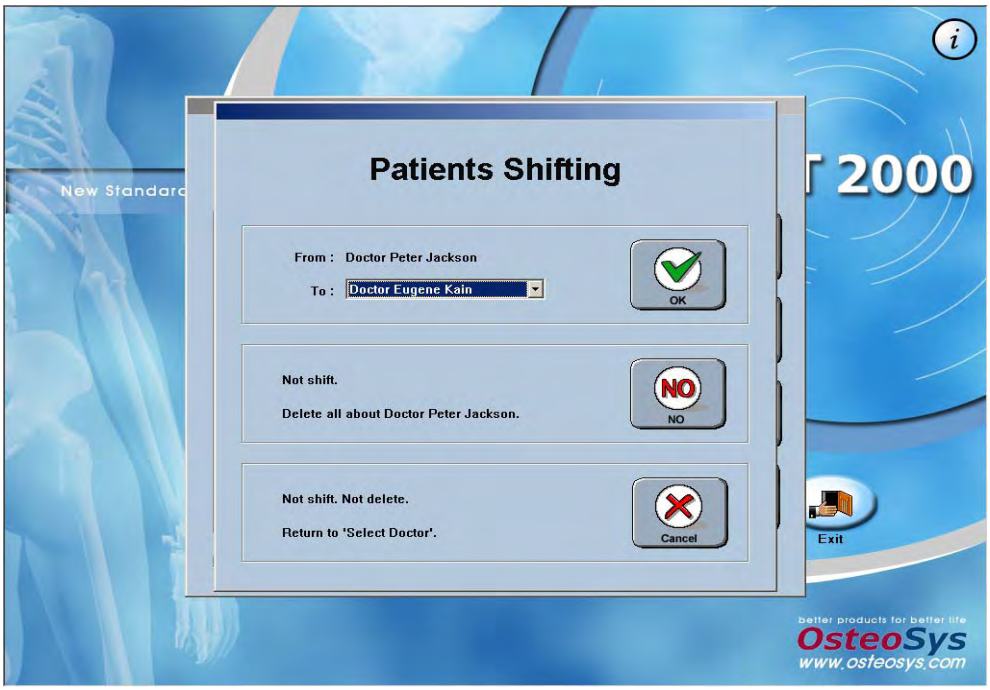
(2) If you are a new user(doctor), click the "New Doctor" button in the "Doctor Selection" window, and then the "New Doctor" window appears. If you enter your information(name, phone number, department and password) and click the "OK" button, the registration process is completed. The log-in process is same as the description "(1)"

(3) If you want to delete registered users, select a desired user and click the "Doctor Delete" button of the "Doctor Selection" window. If there are two or more registered users, the message box "Patients Shifting" inquiring your intention appears as shown below.

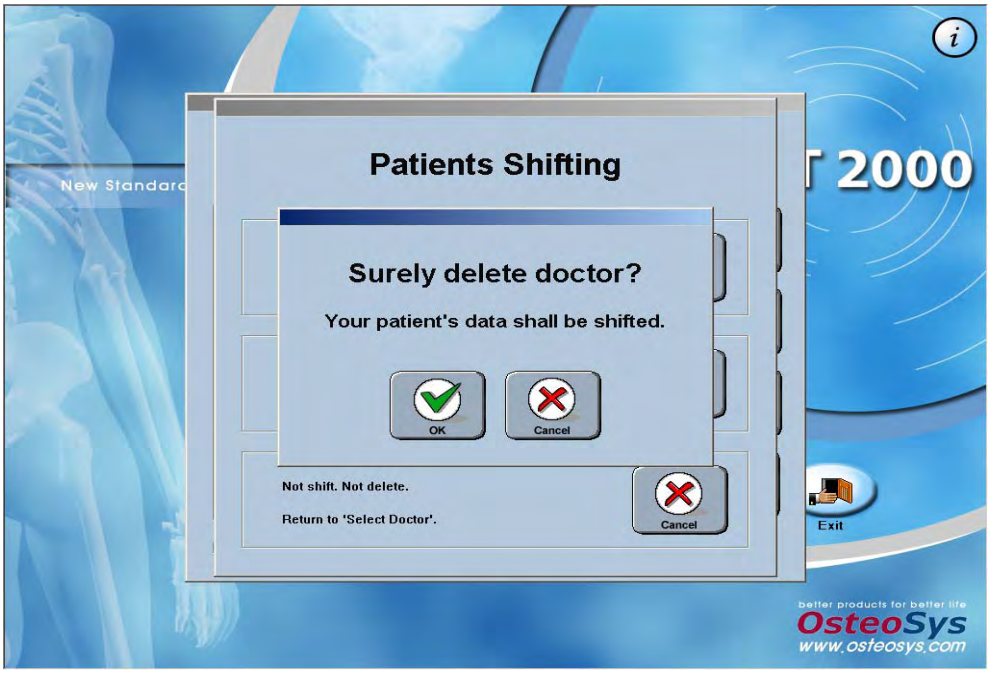
- "OK" : All registered users, except the user you selected to delete, are displayed on the left side of this "OK" button. If you select the user who you want to move the patients' data(the user you selected to delete has measured until now) to and click this button, the data moves to the selected user's DB and the user(you selected to delete) is deleted

- "NO" : If you click this button, the user you want to delete and the patients' data (the user you selected to delete has measured until now) are deleted

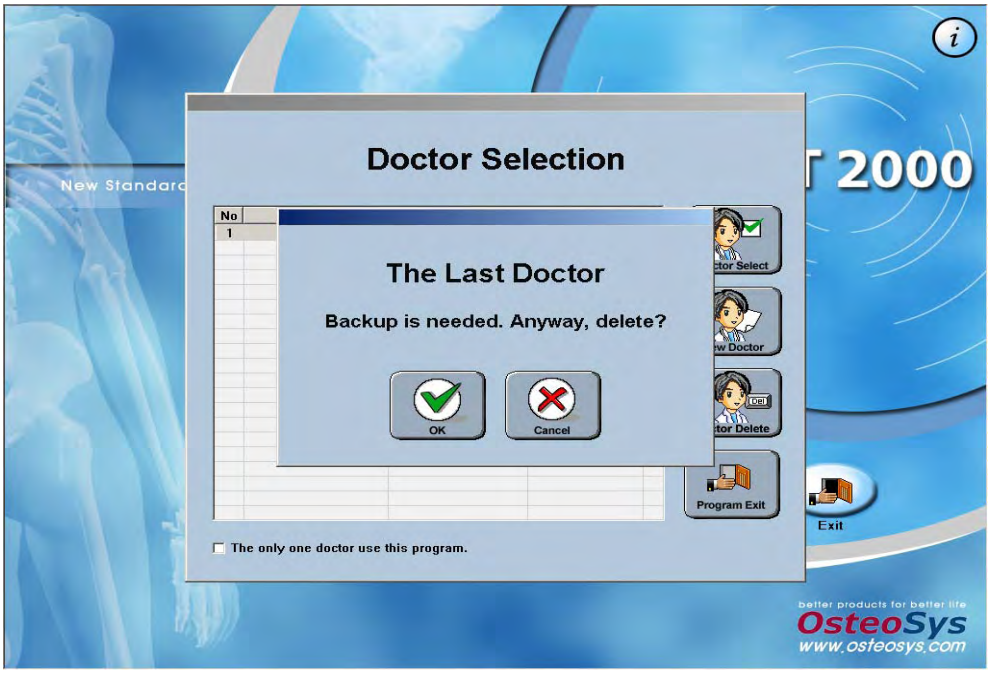
- "Cancel" : If you click this button, you can cancel the deletion process.



(4) If you click the "OK" or "NO" button, the message box "Surely delete doctor?" inquiring whether to delete the user surely appears. If you click the "OK" button the user information is deleted.



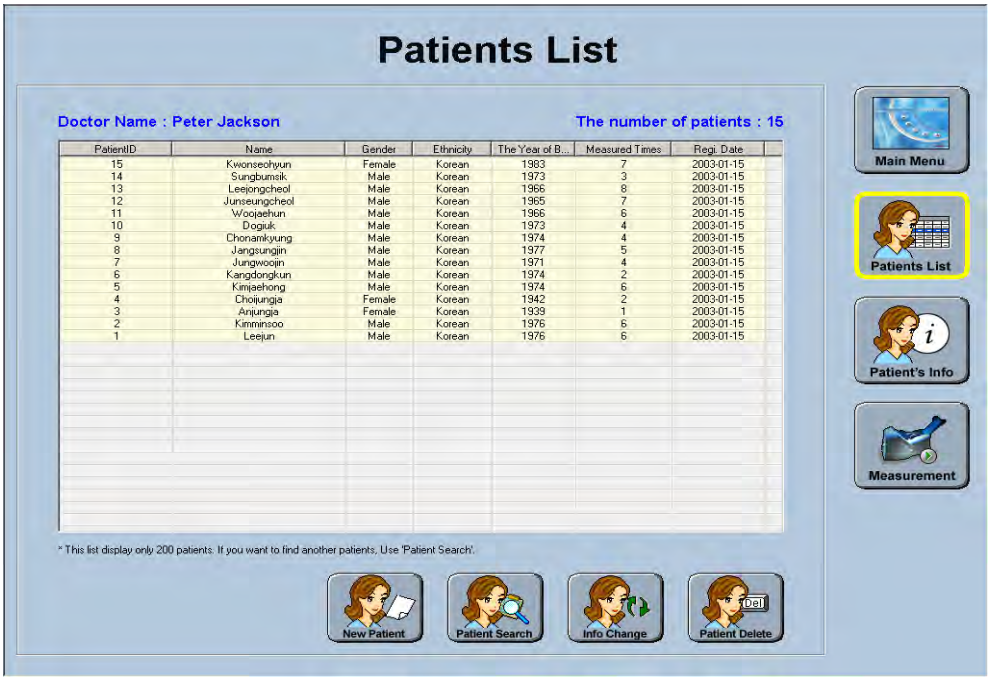
(5) If there is only one registered user when you click the "Doctor Delete" button in the "Doctor Selection" windows, the message box "The Last Doctor" inquiring to advise data backup and to delete the user surely appears. If you click the "OK" button the deletion process starts. If you are only one user, check the checkbox "The only one doctor use this program" on the bottom of the "Doctor Selection" window. Then you can use the system without entering password.



3.2.2.3 BQI Measurement

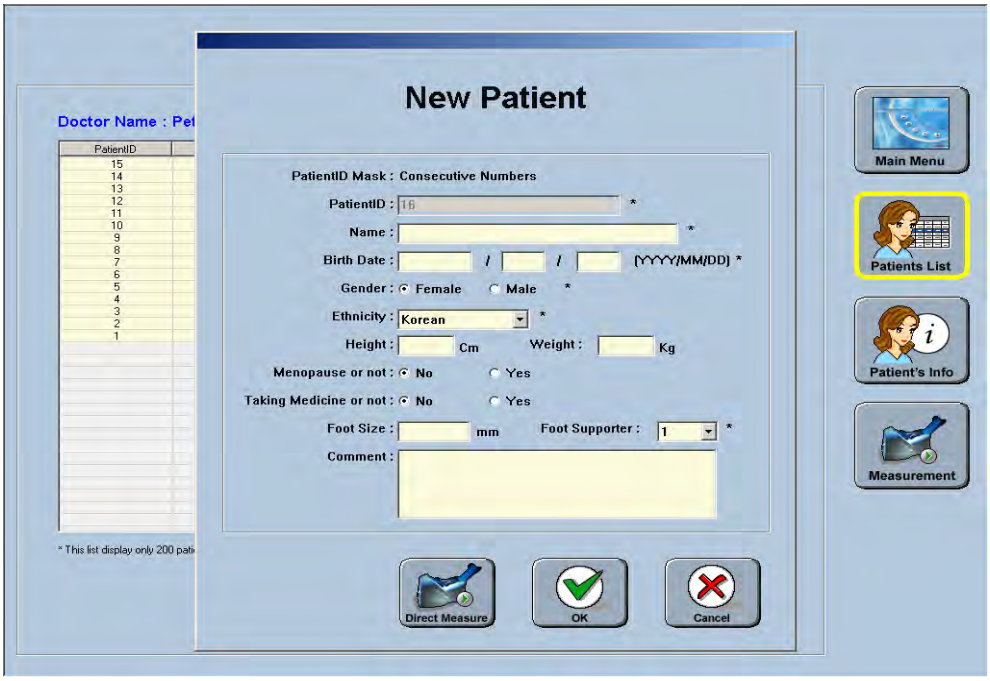
< Registration & Retrieval of Patients >

(1) If you click the "BQI Measurement" button in the default screen, you can move to the "Patient List" screen contains all information of registered patients.


Patients List
Doctor Name : Peter Jackson
The number of patients : 15
PatientID Name Gender Ethnicity The Year of B... Measured Times Regi. Date
15 Kwonseohyun Female Korean 1983 7 2003-01-15
14 Sungbumsik Male Korean 1973 3 2003-01-15
13 Leejongcheol Male Korean 1966 8 2003-01-15
12 Juneeungcheol Male Korean 1965 7 2003-01-15
11 Woojaehun Male Korean 1966 6 2003-01-15
10 Dogiuk Male Korean 1973 4 2003-01-15
9 Chonamkyung Male Korean 1974 4 2003-01-15
8 Jangsungjin Male Korean 1977 5 2003-01-15
7 Jungwoojin Male Korean 1971 4 2003-01-15
6 Kangdongkun Male Korean 1974 2 2003-01-15
5 Kimjaehong Male Korean 1974 6 2003-01-15
4 Choijungja Female Korean 1942 2 2003-01-15
3 Anjungja Female Korean 1939 1 2003-01-15
2 Kimminsoo Male Korean 1976 6 2003-01-15
1 Leejun Male Korean 1976 6 2003-01-15
* This list display only 200 patients. If you want to find another patients, Use 'Patient Search'.
New Patient
Patient Search
Info Change
Patient Delete
Main Menu
Patients List
Patient's Info
Measurement

NOTE !
This "Patients List" screen displays only 200 patients for improving the system speed. If you need to find other patients, use the "Patient Search" menu.

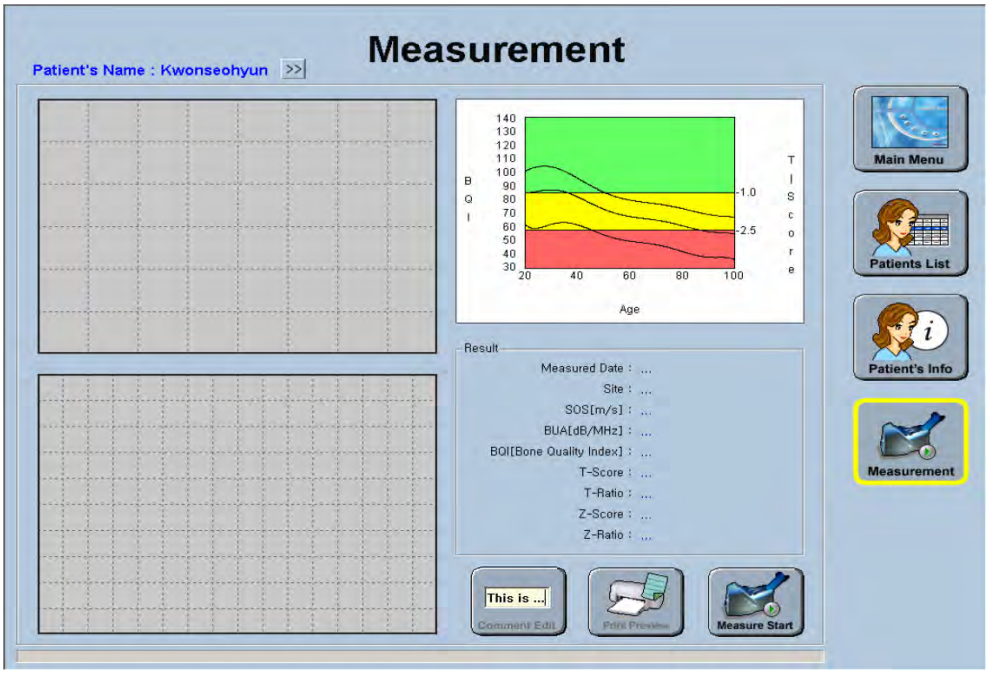
(2) If you want to register new patients, click the "New Patient" button on the bottom of the "Patient List" screen. Then the "New Patient" window you can enter the information of new patients appears. Enter the information and click the "OK" button. Then the patient is registered and the information is displayed.



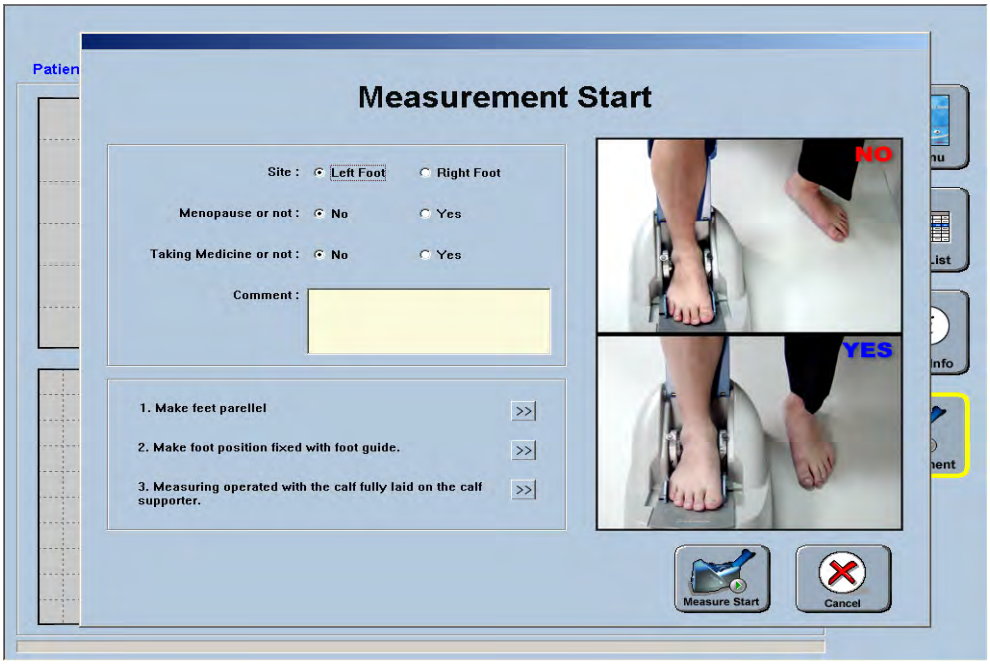
(3) If you want to retrieve registered patients, click the "Patient Search" button, and then the "Patient Search" window contains the retrieval items(name, ID, gender and date of measurement) appears. If you enter the desired patients' information and click the "OK button, then the results appears in the screen.

< Measurement of Patients >

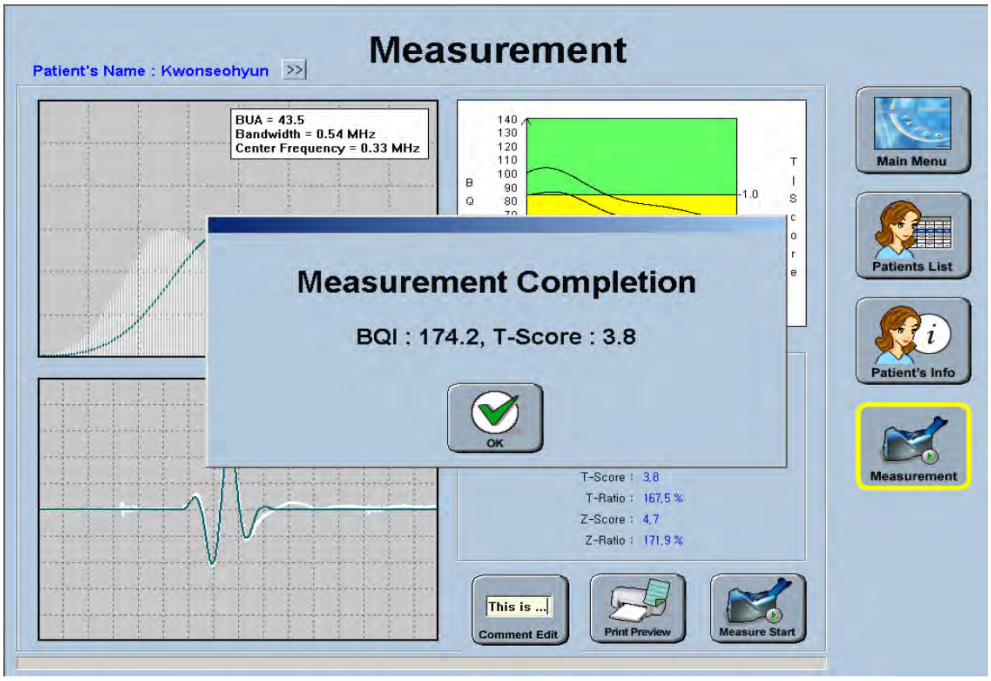
(1) If you want to measure BQI, select a desired patient using the mouse in the "Patients List" screen and click the "Measurement" button on the right side of the screen. Then the "Measurement" screen appears as shown below.



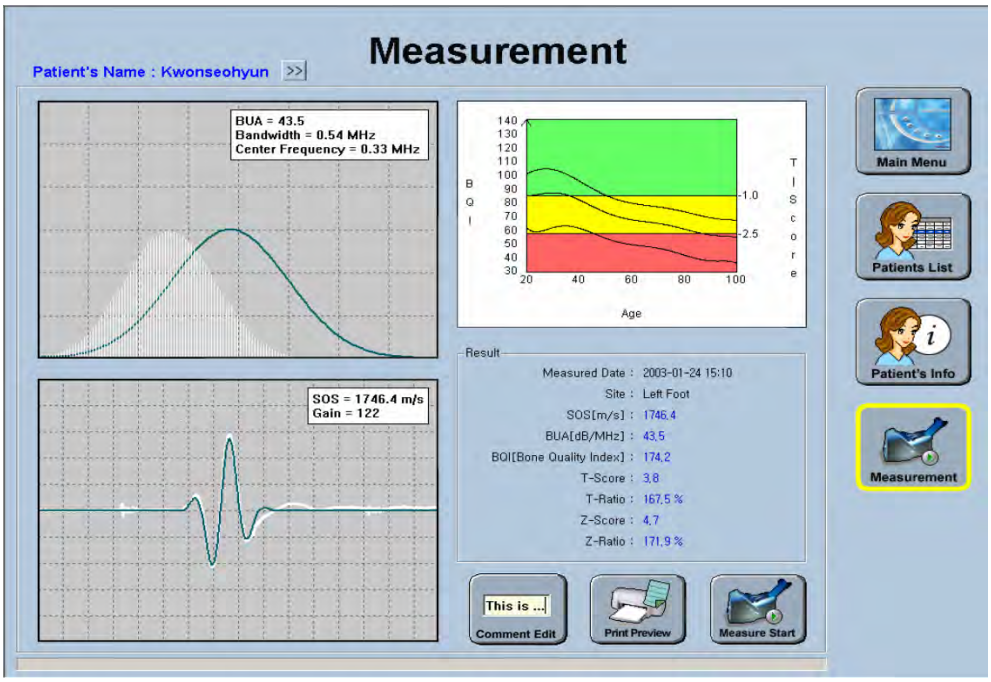
(2) Click the "Measurement Start" button on the bottom of the "Measurement" screen. Then the "Measurement Start" window inquiring measuring site and so on. If you select inquiring articles and click the "Measurement Start" button, ultrasonic waves are generated from the probe.


Measurement Start
Site : Left Foot Right Foot
Menopause or not : No Yes
Taking Medicine or not : No Yes
Comment :
1. Make feet parellel
2. Make foot position fixed with foot guide.
3. Measuring operated with the calf fully laid on the calf supporter.
NO
YES
Measure Start
Cancel

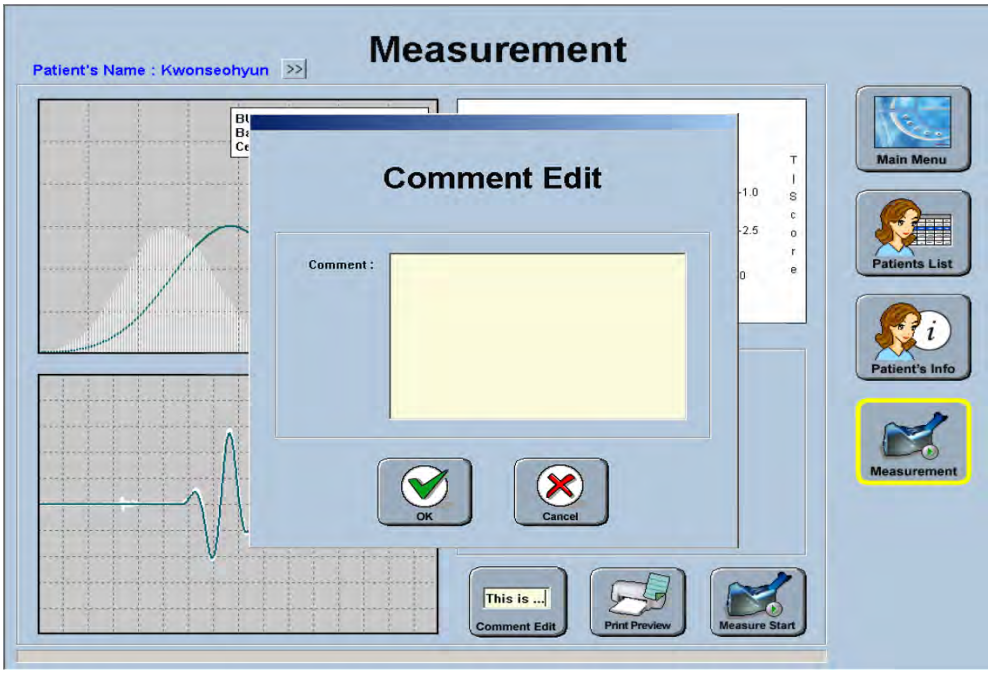
(3) When ultrasonic waves are generated, the word on the "Measurement Start" button is changed into "Measurement Stop". In case of emergency, click this button, and you can stop measuring. In the normal condition, the message box "Measurement Completion" inquiring about whether to restart to measure BQI or not appears with an alarm sound after measurement being finished.



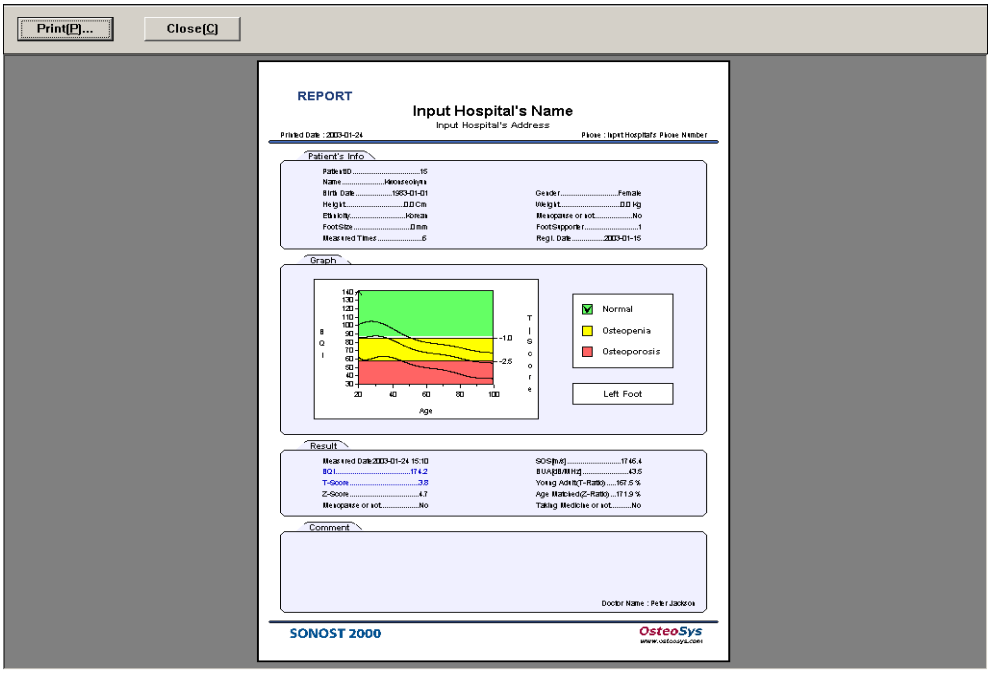
(4) If you click the "OK" button, the results appears in the screen as shown below.



(5) If you need to write or modify comment, click the "Comment Edit" button on the bottom of the screen. Then the "Comment Edit" window, you can write or modify comment.



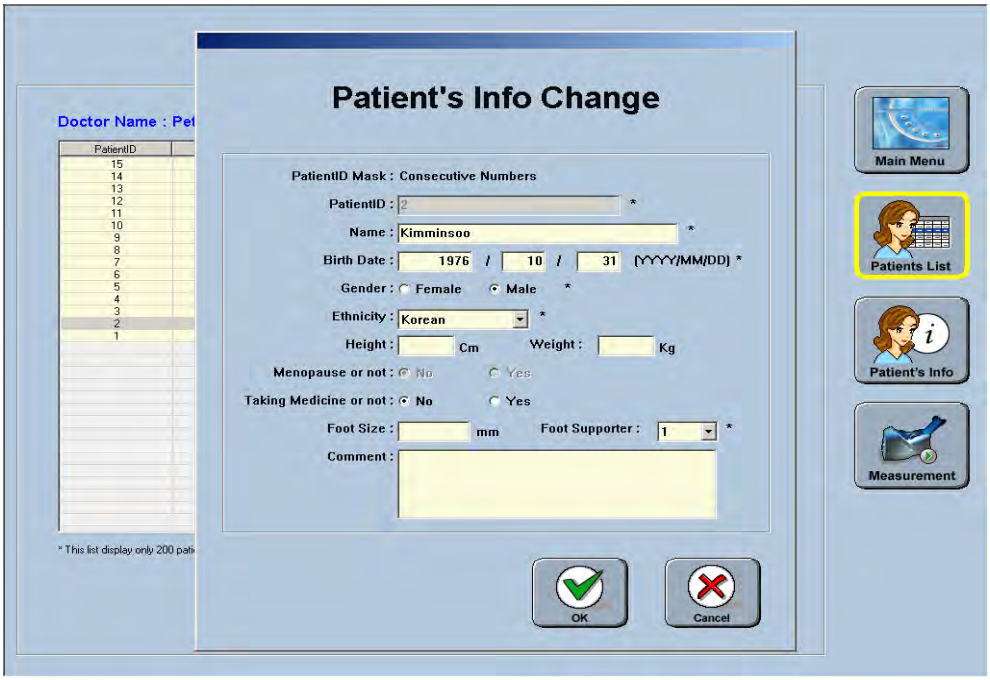
(6) If you click the "Print Preview" button on the bottom of the screen that shows the results after measuring BQI, you can see the results that will be printed out in advance as shown below. If you click the "Print" button on the top of this screen, the results is printed out. The "Print Preview" function can be set in the "Configuration" menu.



3.2.2.4 Revision & Deletion of Patient's Information

(1) If you want to revise the registered patients' information, select a desired patient using the mouse and click the "Info Change" button in the "Patients List" screen.

(2) Then the "Patient's Info Change" screen appears, in this condition, if you enter a new value to make desired changes in the patient's information and click the "OK" button, the patient's information is revised. The changeable patient's information refers to name, date of birth, gender, height, weight, race, menopause state, foot size and so on.

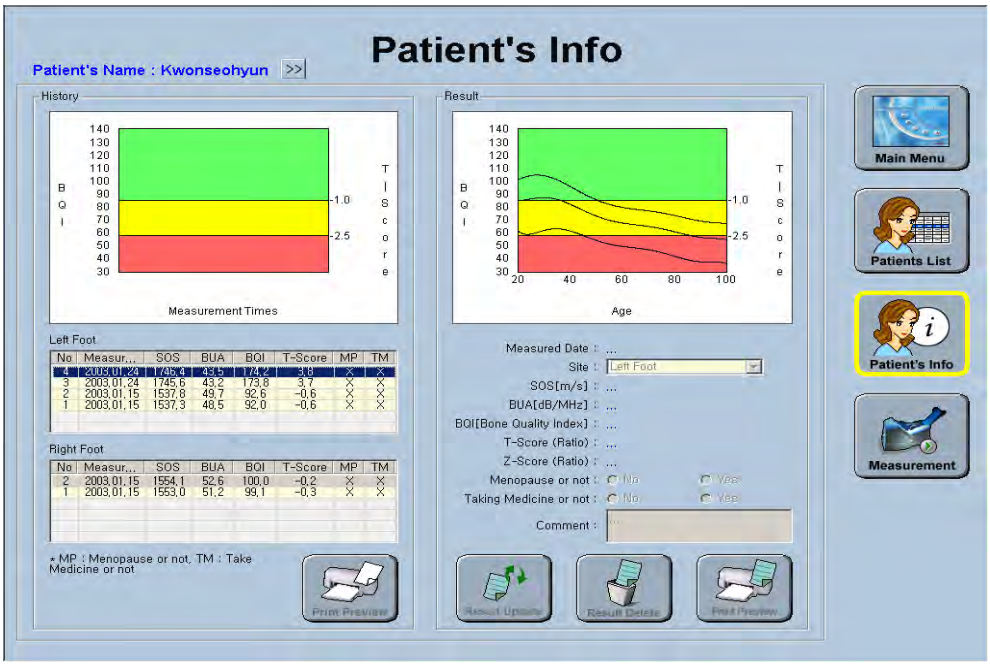


(3) If you want to delete the registered patients' information, select a desired patient using the mouse in the "Patients List" screen. You can select several patients at the same time. To do so, click those patients while pressing the Ctrl key or if you want to select all patients within a certain, click the first and the last line of the area while pressing the Shift key.

(4) After selecting a desired patient, click the "Patient Delete" button on the bottom of the screen. Then the message box "Patient Deletion" inquiring about whether to delete the information surely appears and if you click the "OK" button, the information is deleted.

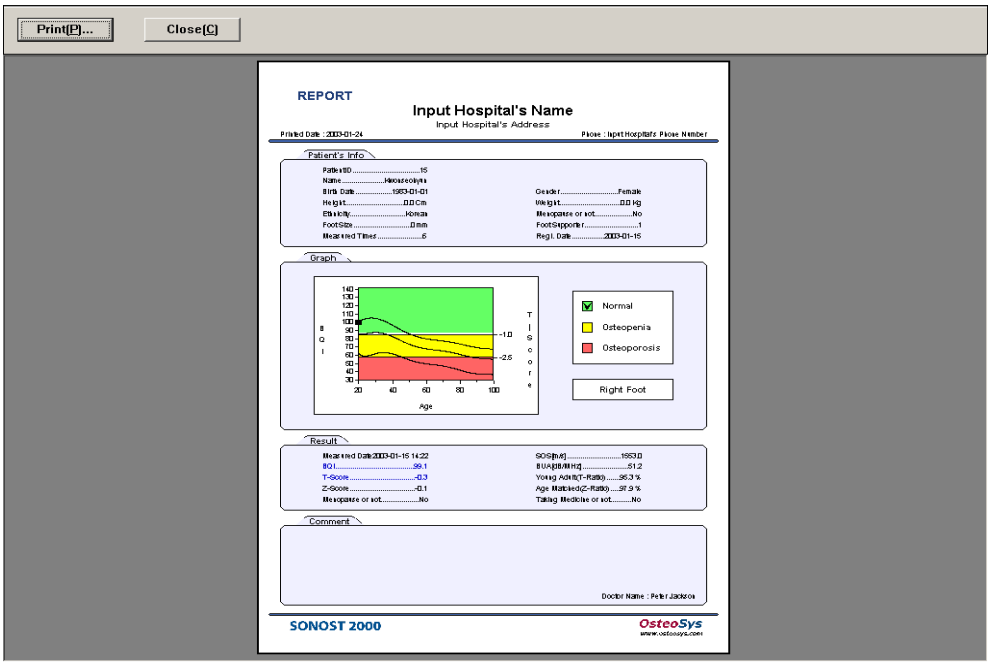
3.2.2.5 Inquiry & Deletion of Clinical History of Existing Patients

(1) If you want to retrieve the clinical history of existing patients, select a desired patient and click the "Patient Info" button on the right side of the "Patients List" screen. Then "Patient's Info" screen appears that contains the patient's clinical history as shown below. On the left & below side, the measurement results list shows. If you select a measurement result in the list, the relevant data appears in the screen.

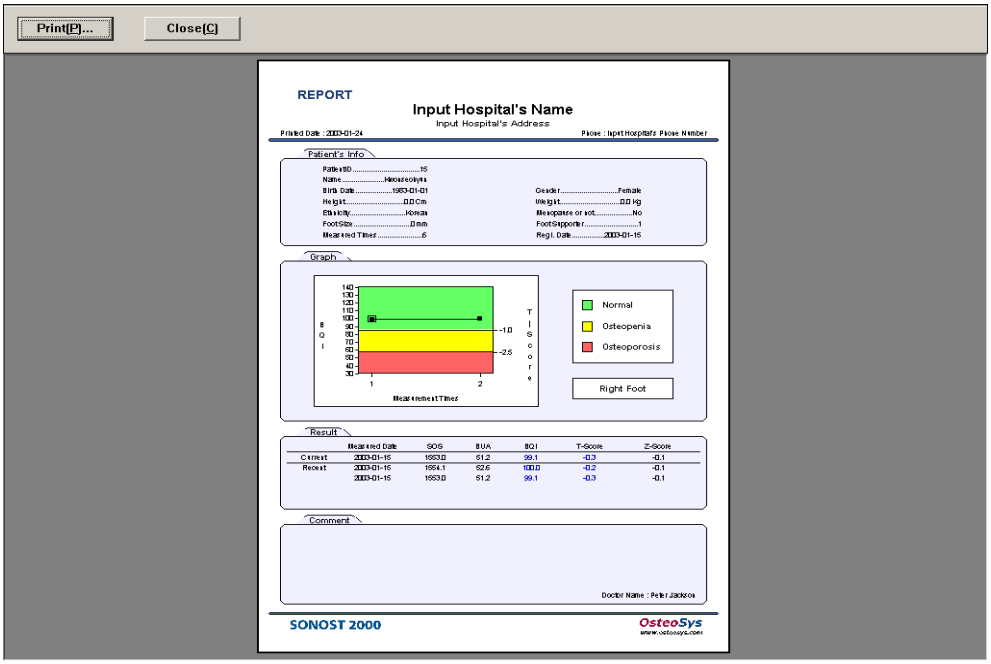


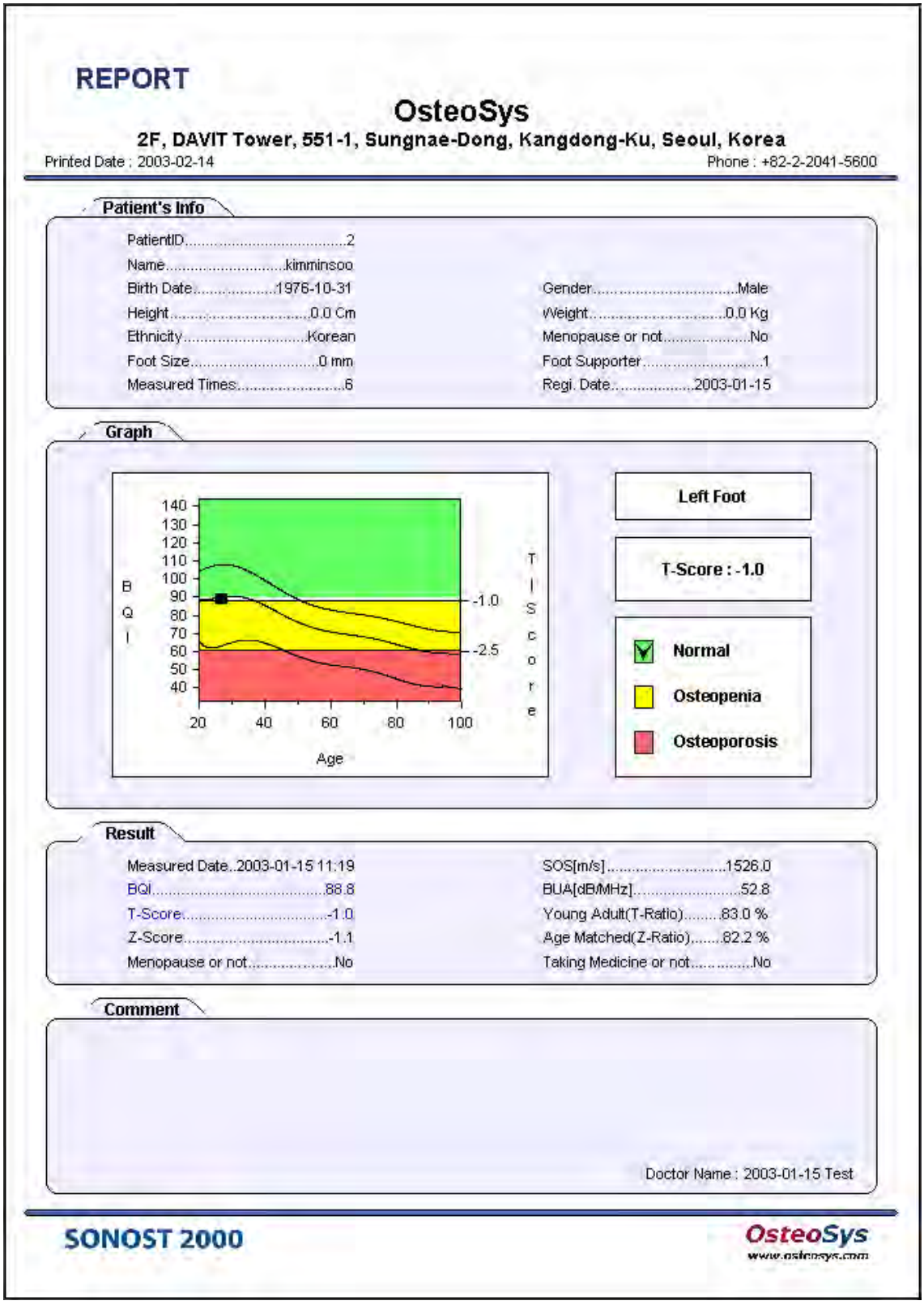
NOTE !
There are two "Print Preview" buttons in the "Patient's Info" screen comparing to the "Measurement" screen, and each button has the different function.

If you click the "Print Preview" on the right side, the result you selected with a mouse appears in the "Patient's Info" screen.

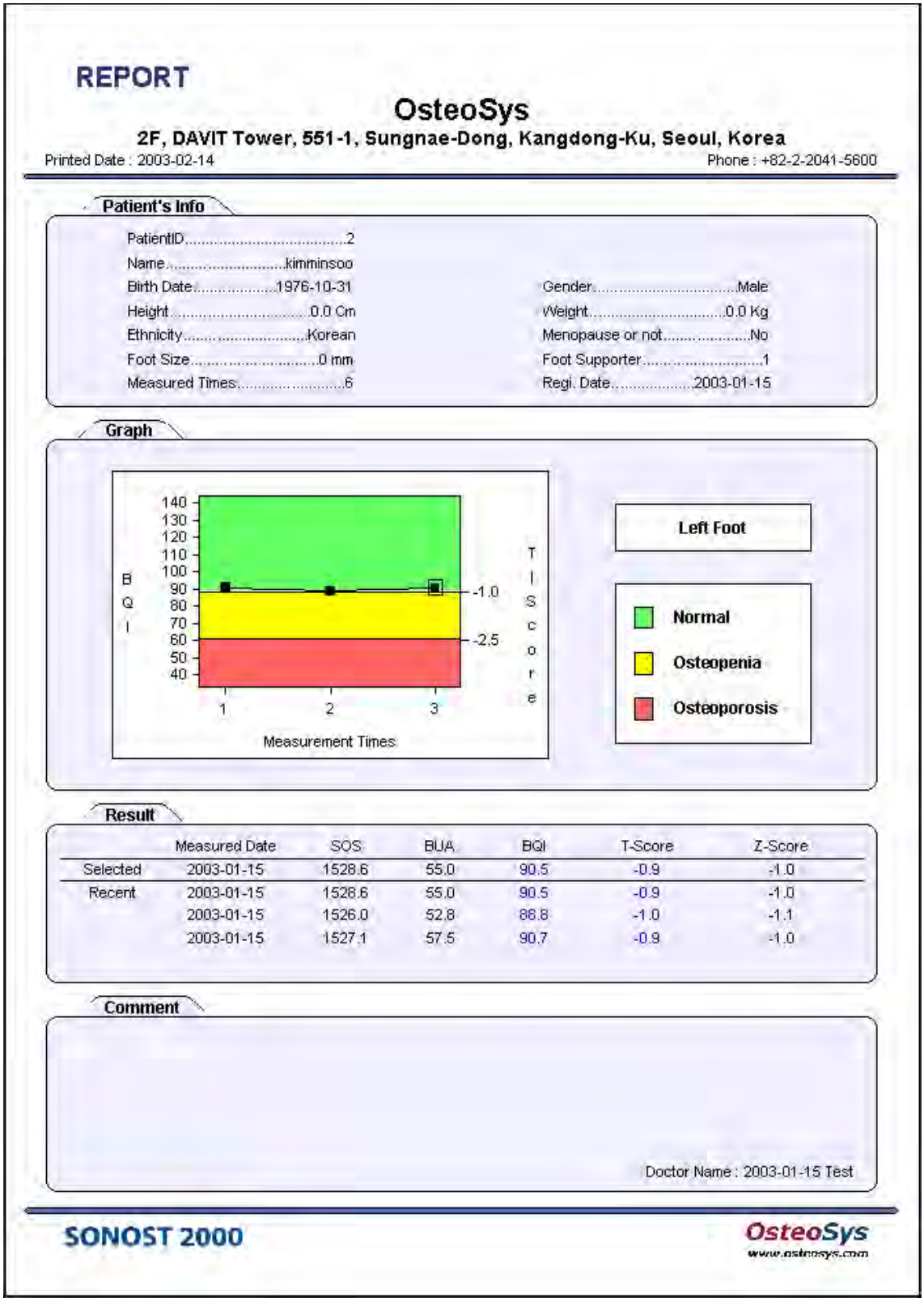


If you click the "Print Preview" on the left side, all results of the selected patient appears in the "Patient Info" screen.





[Print Sample]



REPORT

OsteoSys

2F, DAVIT Tower, 551-1, Sungnae-Dong, Kangdong-Ku, Seoul, Korea

Printed Date : 2003-02-14 Phone : +82-2-2041-5600

Patient's Info

PatientID	2		
Name	kimminsoo		
Birth Date	1976-10-31	Gender	Male
Height	0.0 Cm	Weight	0.0 Kg
Ethnicity	Korean	Menopause or not	No
Foot Size	0 mm	Foot Supporter	1
Measured Times	6	Regi. Date	2003-01-15

Graph

Result

	Measured Date	SOS	BUA	BQI	T-Score	Z-Score
Selected	2003-01-15	1528.6	55.0	90.5	-0.9	-1.0
Recent	2003-01-15	1528.6	55.0	90.5	-0.9	-1.0
	2003-01-15	1526.0	52.8	88.8	-1.0	-1.1
	2003-01-15	1527.1	57.5	90.7	-0.9	-1.0

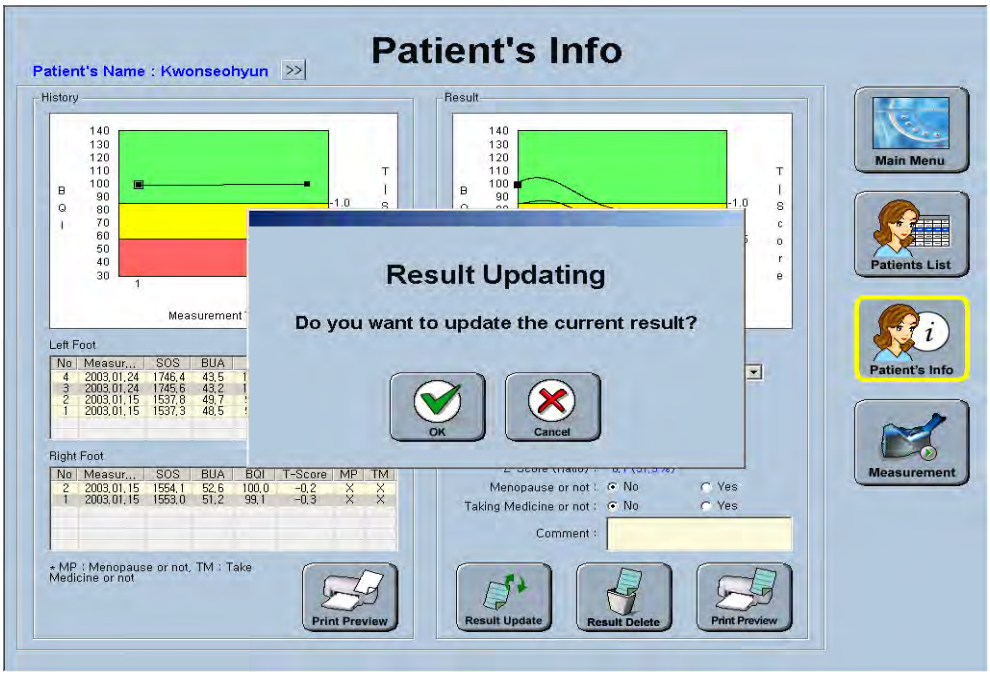
Comment

Doctor Name : 2003-01-15 Test

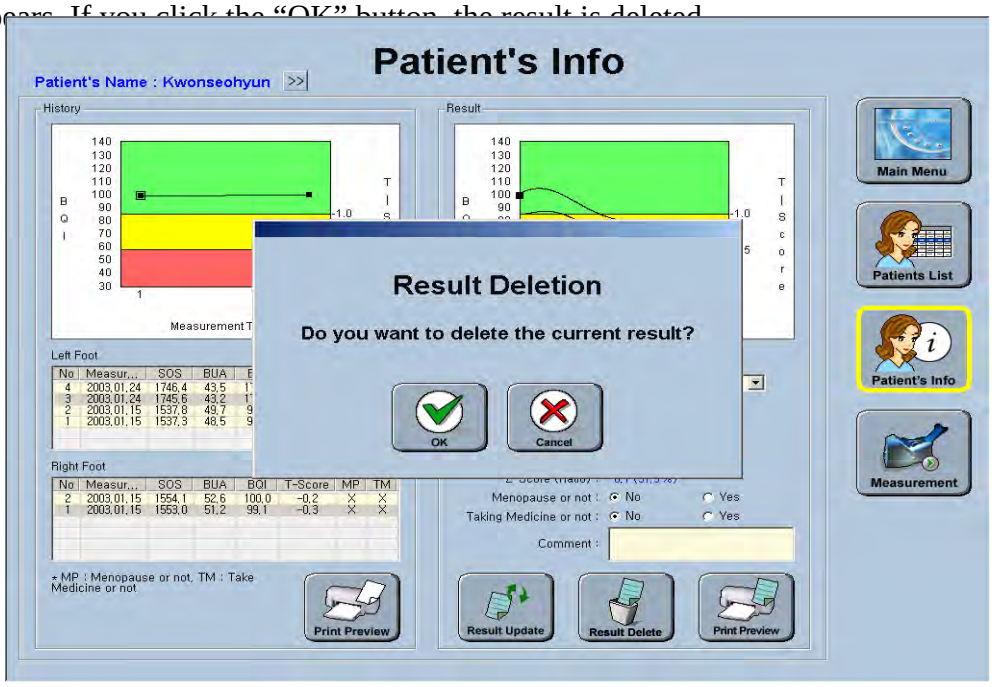
SONOST 2000 OsteoSys www.osteosys.com

[Print Sample]

(2) After revising patients' information(menopause state, taking drug, etc.), if you click the "Result Update" button in the result screen, the message box "Result Updating" inquiring about whether to update the information surely appears. If you click the "OK" button, the relevant history is updated.



(3) If you want to delete the clinical result of patients, select a desired result and click the button "Result Delete" in the "Patient's Info" screen. Then the message box "Result Deletion" that inquiring about whether to delete the result or not appears. If you click the "OK" button, the result is deleted.



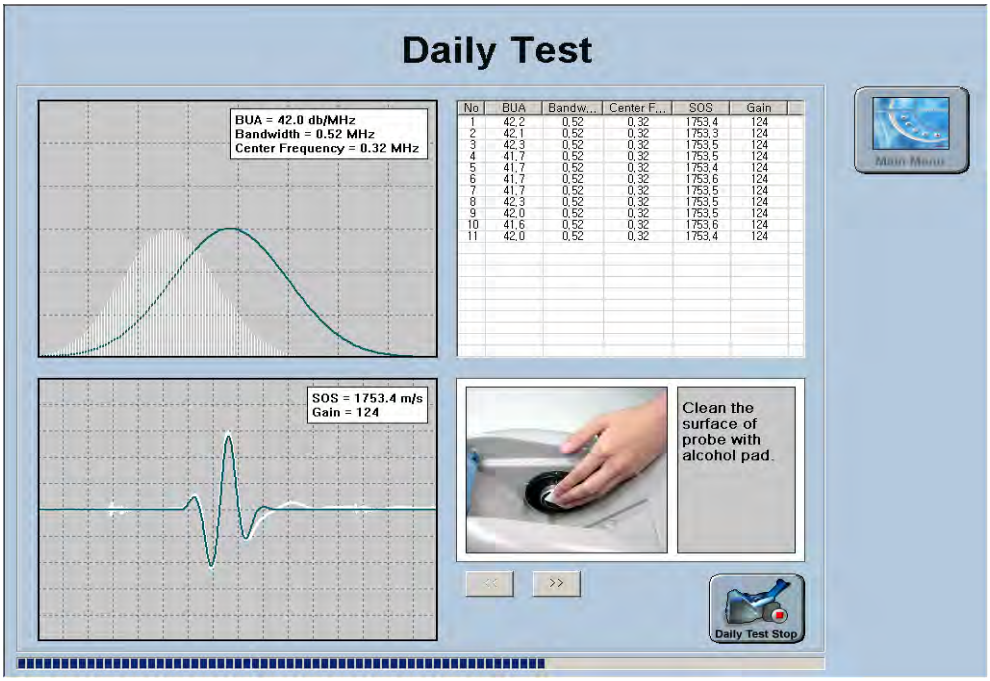
3.2.2.6 Calibration of SONOST-2000

(1) Make sure to calibrate the system to reduce a margin of error and to get accurate values in times of examining bone density. It is to raise credibility of examination results through checking of system reliability on a daily basis.

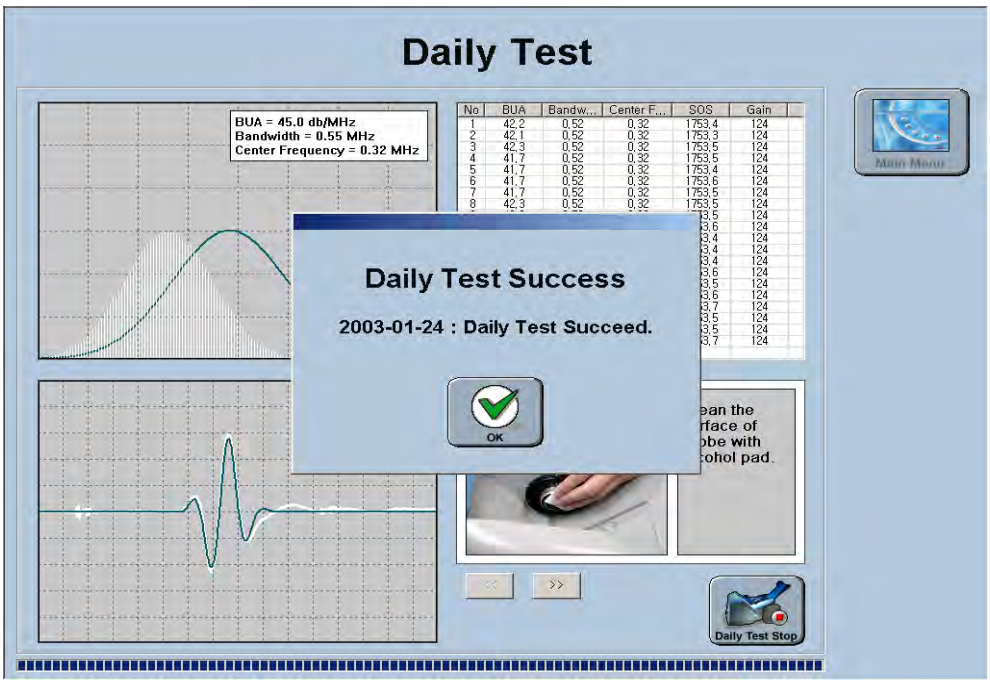
Whenever you calibrate the system, you should use the QC Phantom included in the accessories list.

3.1.2 Using the QC Phantom

(2) To calibrate the system, click the "Daily Test" button in the default screen. Then the "Daily Test" screen appears as shown below. When you click the "Daily Test Start" button in this screen, ultrasonic waves are generated from the probe.



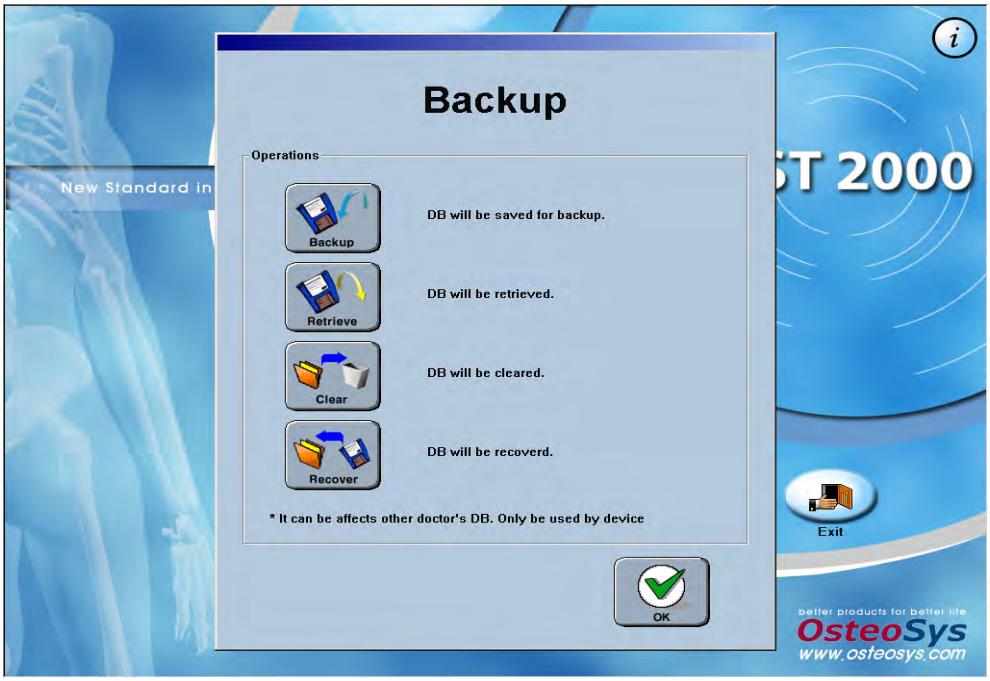
(3) When ultrasonic waves are generated, the word on the "Daily Test Start" button is changed into "Daily Test Stop". In case of emergency, click this button and you can stop daily testing. In the normal condition, the message box "Daily Test Success" appears as shown below with an alarm sound after progressing calibration of the system and if you click the "OK" button, the progress of calibration is completed.



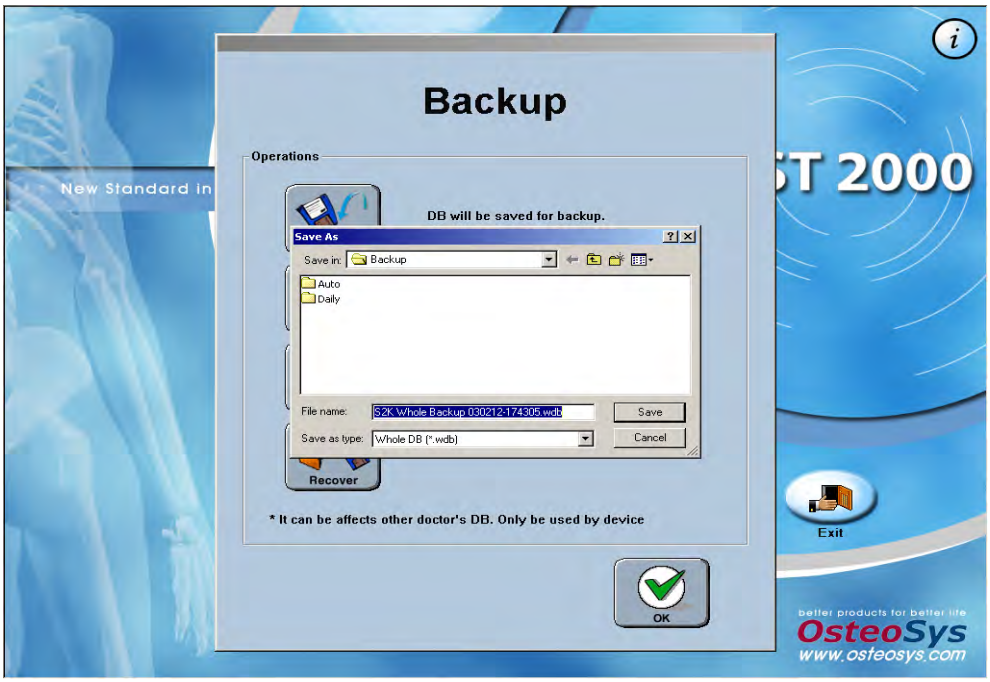
NOTE !
In case of the screen shows the calibration has failed, do not use the system and execute "Daily Test" once again. If calibration fails continually, contact to OsteoSys or its authorized dealer.

3.2.2.7 Data Backup

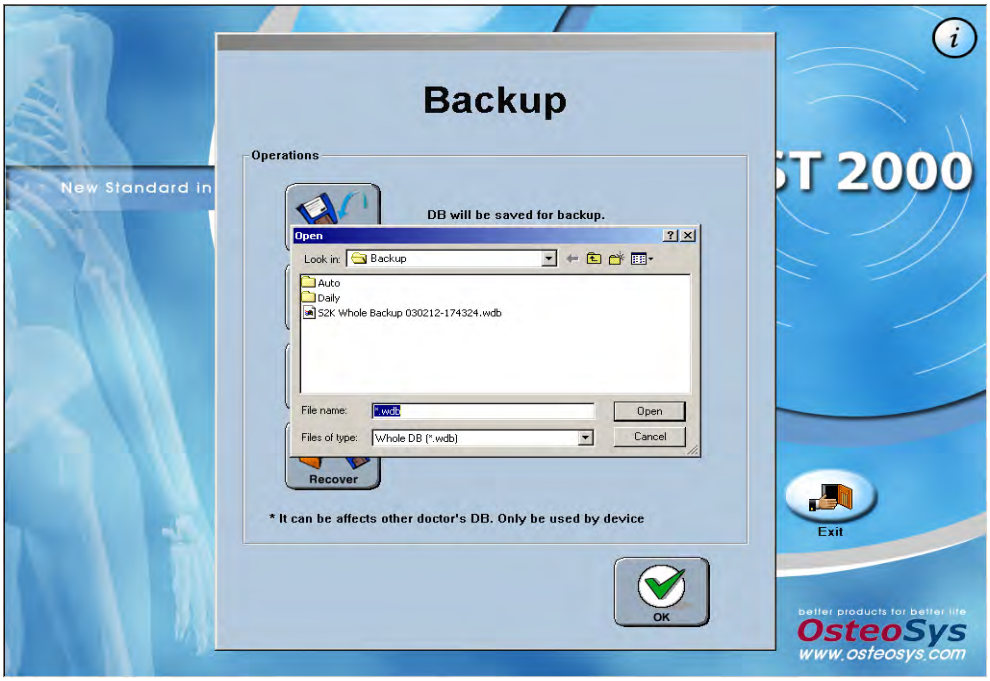
(1) If you need to save the data, click the "Backup" button in the default screen. If you click the button, the default screen of "Backup" menu appears as shown below.



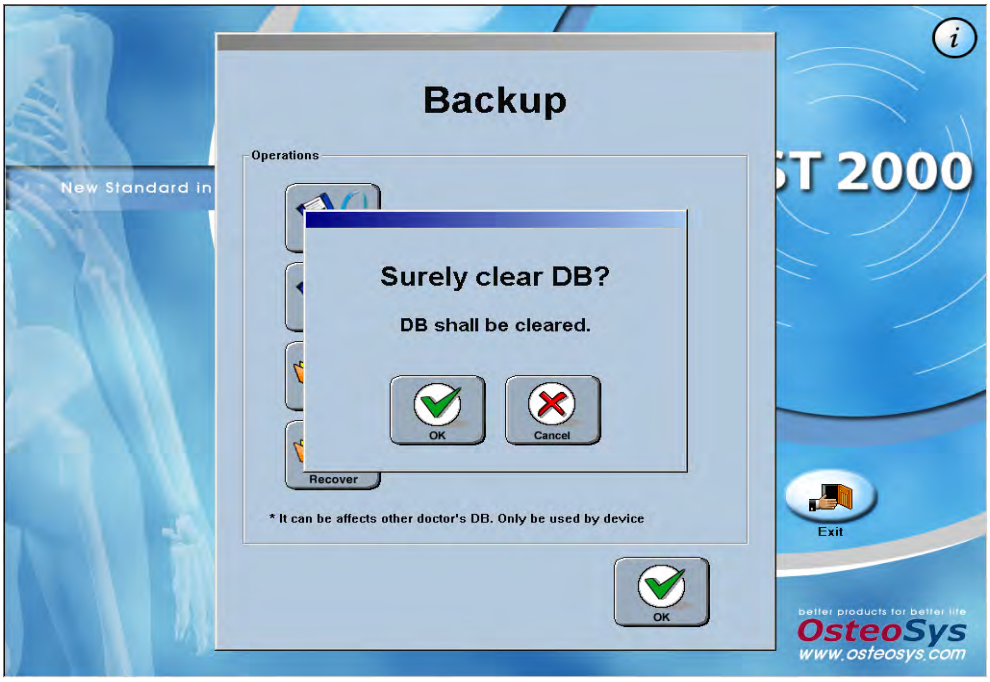
(2) Backup : If you click this button, you can save all users' DB in the PC.



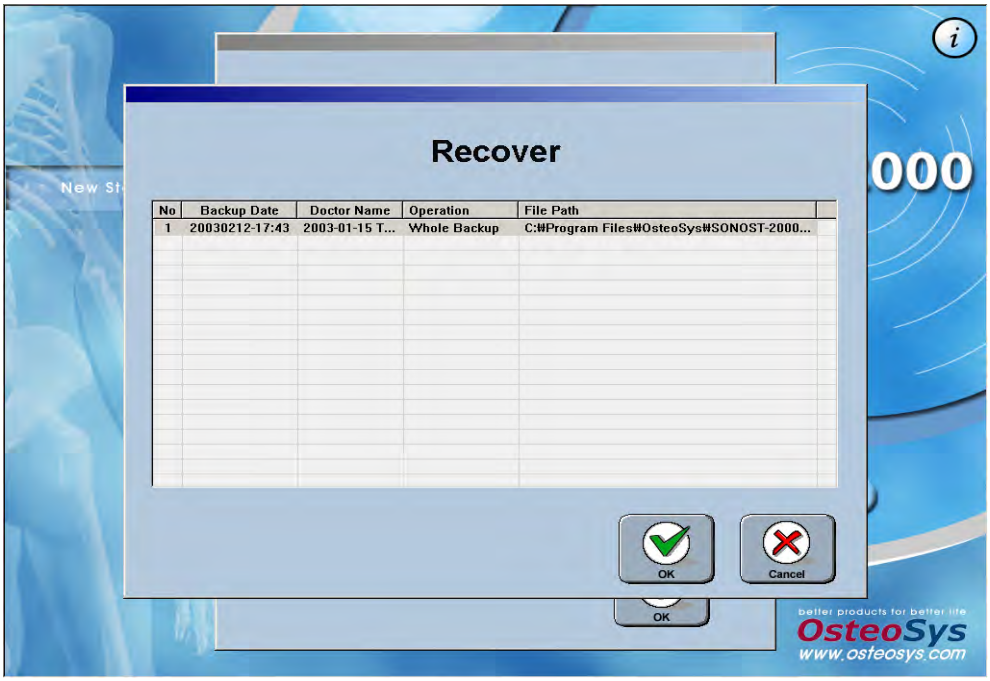
(3) Retrieve : If you click this button, you can exchange all users' DB into others in the PC.



(4) Clear : If you click this button, the message box "Surely clear doctor?" inquiring whether to delete the user surely appears. If you click the "OK" button, you can clear all users' DB.



(5) Recover : If you click this button, you can recover all users' DB.
All records related the DB are written in this field.
After selecting the record and clicking the "OK" button in this screen,
the DB is recovered.

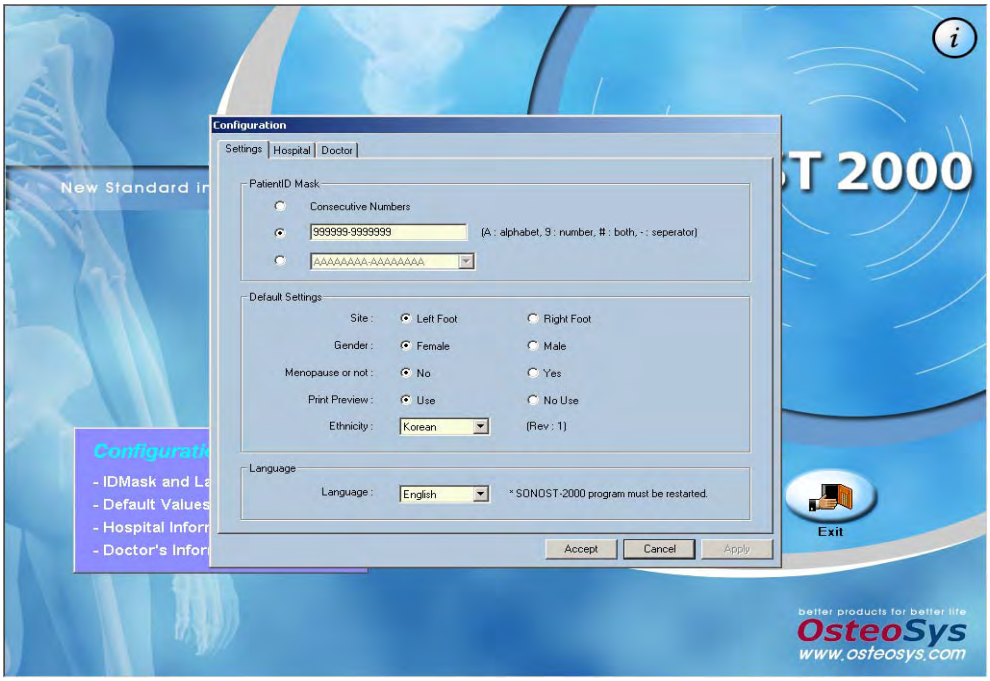


3.2.2.8 Configuration of Environment

(1) If you want to configure the user environment again, click the "Configuration" button in the default screen. There are four items from "Settings" to "Doctor" in this menu.

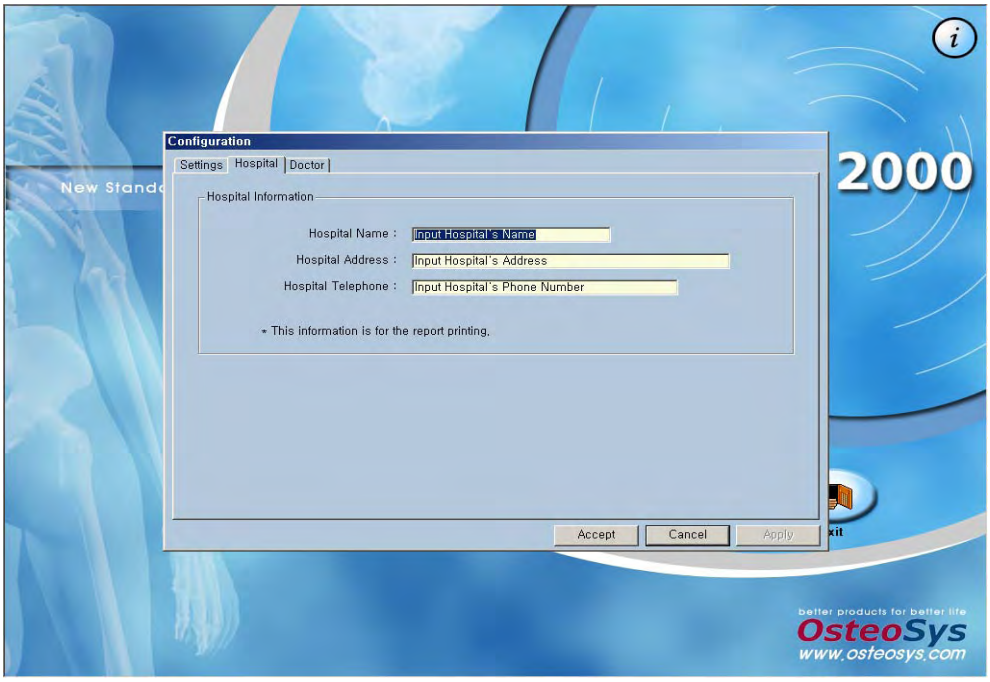
(2) Settings :

3.2.2.1 Execution of Program and Configuration of the Incipient Environment

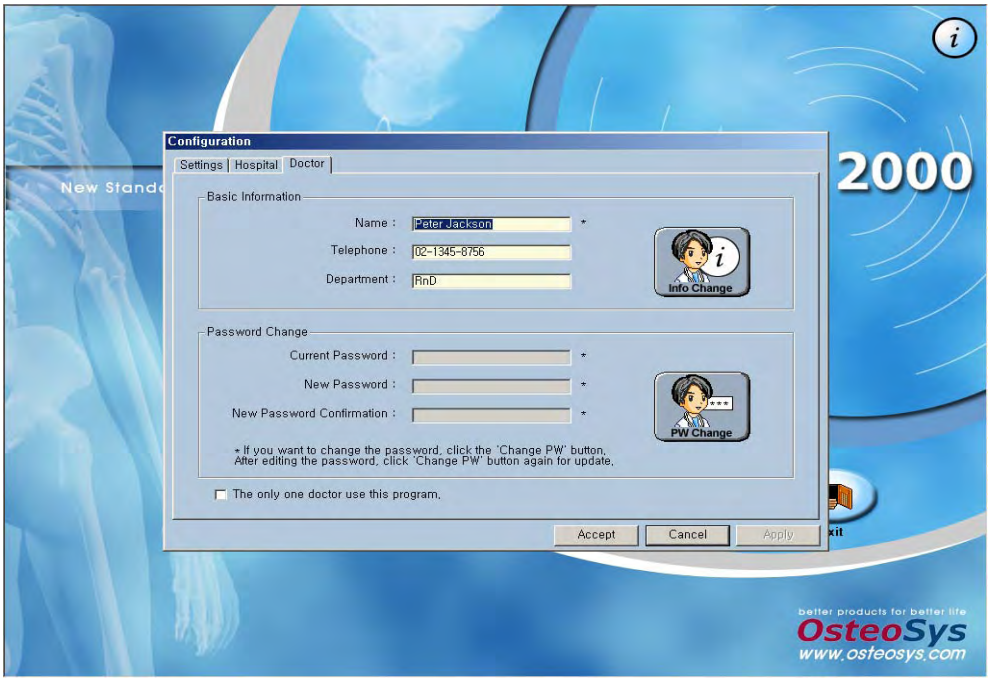


(3) Hospital :

3.2.2.1 Execution of Program and Configuration of the Incipient Environment



(4) Doctor : You can set your name, phone number and department. If you click the "PW Change" button, you can change your password.



3.2.2.9 Inactivation of SONOST-2000

If you click the "**Exit"** button in the default screen, the message box "Program Exit" inquiring about whether to exit the program appears and if you click the **"Ok"** button, the program is inactivated.

Chapter 4. Maintenance and Repair of SONOST-2000

4.1 Resolution to Problems

4.2 Maintenance and Repair

4.2.1 Cleaning

4.2.2 Stockpile and Replacement of Articles

4.2.3 Storage

4.3 Safe Use of SONOST-2000

4.3.1 Safety Rules

4.3.2 Cautions Related to Use of Electronic Medical Equipment

4.1 Resolution to Problems

If SONOST-2000 shows following symptoms, check the system as follows.

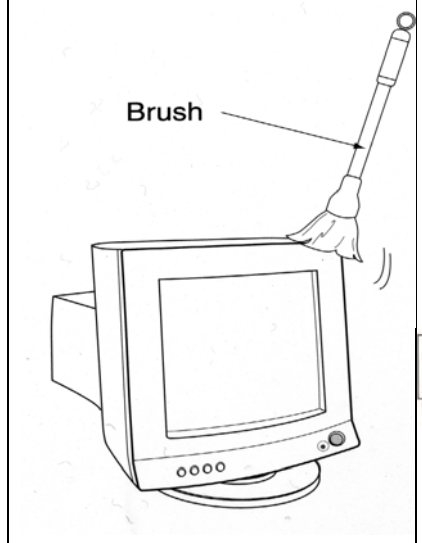
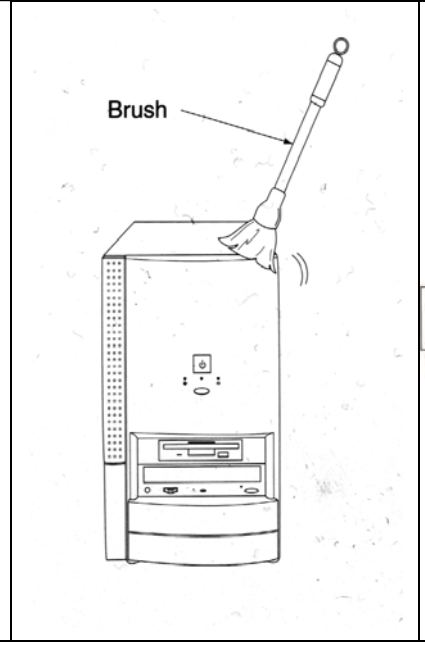
Problems	Checking points
SONOST-2000 is not activated with the power on.	Is the device properly plugged?
	Isn't the power cord damaged?
	Aren't the fuses gone?
Computer is not activated with the power on.	Is the device properly plugged?
	Isn't the power cord damaged?
Monitor is not activated with the power of the computer on.	Is the monitor switched on? User's instructions of monitor
Screen of the monitor is not bright enough.	Adjust brightness. User's instructions of monitor
Result of calibration of the system turns out to be abnormal.	3.2.2.6 Calibration of SONOST-2000
Result of measurement turns out to be abnormal	3.2.2.3 BQI Measurement 3.2.2.6 Calibration of SONOST-2000
Despite measurement according to the instructions, its result turns out to be abnormal	Is the desired part of the body properly placed?
	Are the balloons adjusted properly?
	Are bubbles in the balloon?
	Is the hardened gel ticked on the surface of the balloons 4.2.1 Cleaning
The balloons tears easily	Is some material on the surface of QC phantom?

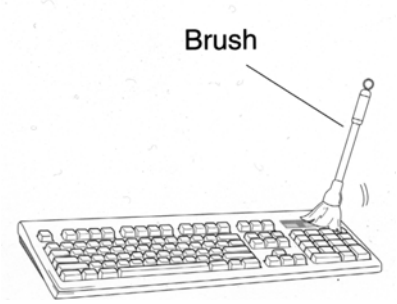
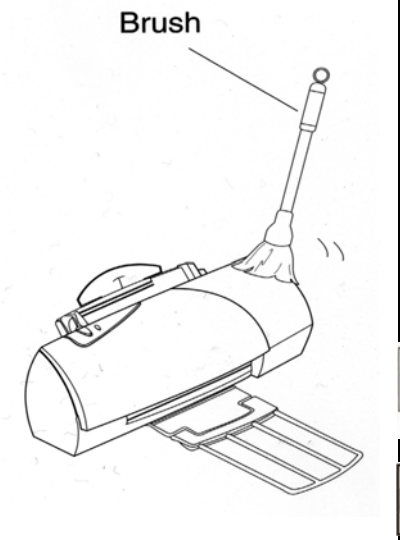
CAUTION !
If you cannot resolve the problem, contact to OsteoSys or its authorized dealer.

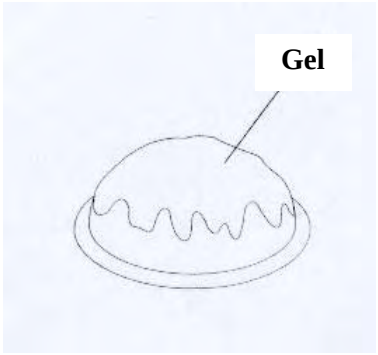
4.2 Maintenance and Repair

4.2.1 Cleaning

CAUTION !
Turn off the power before cleaning the system.

Product	Example	Instructions
Monitor		Dust the monitor with a soft brush every day. Clean the screen of the monitor with a soft cloth. If there is a strong stain on the cover, soak a clean and soft cloth with neutral detergent diluted with water in about a ratio of 5 to 1, and dry the cloth and remove the stain with it. And then wipe out the stained area with soft and dry cloth again. Make sure not to put water or detergent on the monitor directly. Water or detergent can damage the monitor. If you use volatile chemicals such as benzene or thinner, surface of the monitor can be damaged.
Computer		Dust the computer with a soft brush everyday. If there is too much dirt on the computer, soak a clean and soft cloth with neutral detergent diluted with water in about a ratio of 5 to 1, and wring water from the cloth and wipe out dust. Make sure not to put water or detergent on the computer directly. Water or detergent can damage the computer. Make sure not to use volatile chemicals such as benzene or thinner because it can damage the surface of main body of the computer.

Product	Example	Instructions
Keyboard		Dust the keyboard with a soft brush. Direct contact with water or detergent can damage the key-board.
Printer		Remove paper from the printer and dust the printer with a soft brush carefully. If there is strong stain on the printer, soak a clean and soft cloth with neutral detergent diluted with water in about a ratio of 5 to 1, and wring water from the cloth and wipe out dust. And then clean the stained area with dry cloth. Cover the printer with printer cover to avoid water. **User's instructions for printer**
Device		After using the device, remove the balloons from the device and wash with water. The device should be cleaned with a water wringed clean soft cloth everyday, because gel remains around the probe or below the device. Especially, gel stained on the balloons should be moved. After this procedure, clean the stained area with a dry piece of cloth. Make sure not to put water or detergent on the device directly because it can cause fatal damage in the electric circuit contained inside.

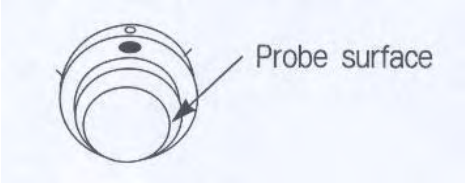
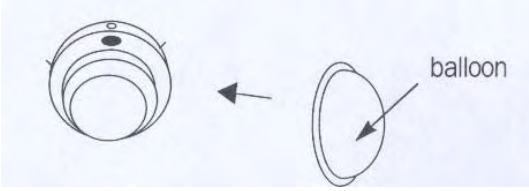
Product	Example	Instructions
Balloon		After using the device, remove the balloons from the device and wash them with water.

4.2.2 Stockpile and Replacement of Articles

Make sure to keep following articles of consumption all the time.

2.1.5 Articles List

Articles	Specifications
Printing Paper	Use white A4 paper. Refer to user's instructions for details.
Ink Cartridge	Replace ink cartridge with a new cartridge if the printed text or picture is not vivid enough. **User's Instructions for Printer**

Articles	Specifications
Gel	Gel is a necessary article when measuring BMD. Please purchase new one before it being out of stock.
Balloon	Purchase ones at our authorized dealer when it needs to be used. **< Replacement procedure of the balloon >** 1. Remove the hardened gel from the probe.  2. Clean the surface of the probe with an alcohol pad. 3. After attaching the balloon to the probe holder, Adjust the balloon housing to the probe holder.  4. After taking water into the balloon, close it with the stopper. 5. Check the surface of the probe through the balloon. Tap the balloon to remove bubbles inside of the balloon.

4.2.3 Storage

Daily storage	1) Unplug the power cord. 2) Dust on the product can damage the system. After use, make sure to cover it with a vinyl cover. 3) If the hardened gel remains in the device, it can effect on BMD results. Please clean the device everyday. **4.2.1 Cleaning**
Storage for a long time of period	1) Unplug the power cord. 2) Do not detach cable of the device connected to plug to prevent dust from coming inside. Place cable near the product or at an empty area in its front. 3) Put cover on the product to avoid dust. 4) Keep the product according to instructions described in **"2.2 Installation of SONOST-2000"** **2.2 Installation of SONOST-2000**

4.3 Safe Use of SONOST-2000

4.3.1 Safety Rules

The followings are instructions for safe use of the product
Make sure to comply with the instructions when you activate the system.
Refer to "4.3.2 Caution related to electronic medical equipment"

4.3.2 Cautions Related to Use of Electronic Medical Equipment

CAUTION !	➢ Do not open it because there are some high-tension components inside. It might cause serious danger. ➢ Check if the cable coating is not damaged before turning on the system to prevent electric shock or leakage of electricity. If it is damaged or broken, immediately contact an agency. ➢ Do not share the power outlet with other products. If you share the outlet it will affect the product.
CAUTION !	➢ Read user's instructions carefully before using the product. ➢ Place the user's instructions at a designated place so that users can read it anytime they need it. ➢ If you hear a strange noise or if you find any abnormality on the screen after turning on the product, contact the headquarters or an agency. ➢ Make sure to turn off the power switch before cleaning the product.

4.3.2 Cautions Related to Use Electronic Medical Equipment

Safety rules described below are based on Paragraphs 495 of laws and ordinances promulgated by Ministry of Welfare of Japan. The safety rules pertain to use of electric medical equipment. Read them carefully for safe use of the product and make sure to refer to **"4.3.1 Safety rules"**

4.3.1 Safety Rules

Nobody can handle SONOST-2000 except for doctors and authorized personnel

Comply with followings in times of installation of SONOST-2000. Do not install it in following places.

A) Places where the product is exposed to water vapor
B) Places where the product is exposed to spray or splashing water.
C) Places where the product is exposed to high density oil vapor
D) Places where the product is subject to excessive shocks or vibrations.
E) Places where the angle of inclination of the mounting surface exceeds 10 degrees.
F) Places where air pressure, temperature or humidity drastically changes.
G) Places exposed to direct sunlight or places where air is polluted due to dirt, salt and sulfur
H) Places where chemicals are kept or toxic gas is leaked.
I) Places where the AC power line voltage fluctuates heavily
J) Places where the AC power line voltage fluctuates heavily while this product is operating.
K) Places where there is a ventilation problem.
L) Do not lean, shake or rock the product during transportation.
M) Adjust frequency, voltage or current to the product.
N) The product is portable but make sure to put a brake on it when you stop the product.
O) Ground the product by using ground wire.
P) Do not share the power outlet.

Check followings before using the product.

A) Whether power is off before putting a plug in the socket.

B) Whether the power supply line is suitable with that of the system (AC 100~240 V)

C) Whether the system is fully grounded.

D) Whether all the connection parts(power and optional equipment) are connected with the system properly.

2.3 e Turning on Power

E) The product has been factory-set for optimum performance. Do not attempt to adjust any preset controls or switches except for operation as specified in this manual.

F) If you experience any trouble with the product, turn it off immediately and contact OsteoSys or its authorized dealer for assistance.

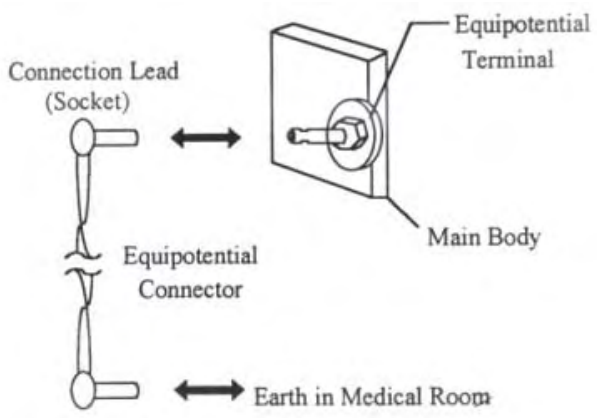
G) Before electrically or mechanically connection any other manufactures' devices to SONOST-2000, contact OsteoSys or its authorized dealer for instructions

H) Do not operate the product improperly when you use it with other products.

I) Make sure to check whether external parts of the device directly touches the patient.

J) Make sure to check whether the products keep distances at least 10cm from walls.

CAUTION !
Equipotential Bonding In hospital, doctors and patients are subjected to dangerous, uncontrollable compensating currents. These currents are due to the potential differences between connected equipment and touchable conducting parts as found in medical rooms. The safest solution to the problem is accomplished is consistent equipotential bonding. Medical equipment is connected with connecting leads made up with angle sockets to the equipotential bonding network in medical rooms.



NOTE !

Try to place the system far from power generators, X-ray machines, broadcasting stations, and transmission lines to avoids electrical noise during scanning. Otherwise, abnormal images may result. An independent circuit and a safely grounded outlets are strongly recommended for SONOST-2000. Poor or abnormal images may occur if the system shares a power source with other electrical or electronic equipment.

NOTE !

The classification according to standard IEC/EN 60601-I

- Type of protection against electric shock : Class I
- Degree of protection against electric shock : Type B
- Degree of protection against harmful ingress of water : IPX 0
- Methods of sterilization or disinfection : See Chapter 4.2.1
- Not suitable for use in the pressure of flammable anesthetic mixtures

Check followings while the device is in operation.

A) Whether the product and the patient are normal

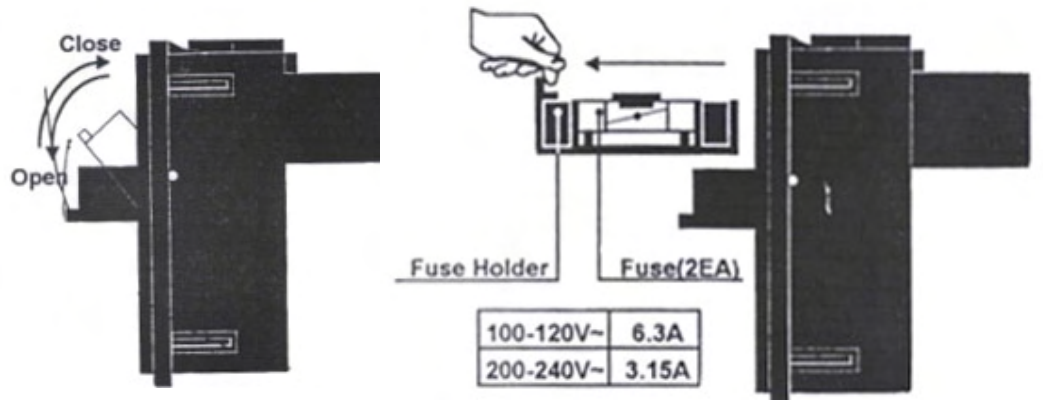
B) Whether the products keep distances with one another

C) If you find any abnormality related to the product or patient, stop its operation and check if it can cause any danger to the patient.

D) If the fuses are gone, exchange the same type (250V T315AL). Otherwise a fire may occur or you may receive electric shock.

NOTE !

Fuse Replacement



1. Open the fuse drawer on the upper side of the appliance inlet, there will be the two small fuse holder.
2. Push the fuse holder toward the arrow direction, and Pull the fuse holder toward the upper side of the appliance inlet.
3. Remove the old fuse by pulling up
4. Install the new fuse by pushing to the fuse holder.
5. Insert the fuse holder to the appliance inlet. At this time, the arrow direction in the upper side of the fuse holder should be in accordance with that on the fuse draw.
6. Also, the same method is used to exchange the other fuse folder.
7. Close the fuse the drawer.

CAUTION !

For continuous protection against a risk of fire hazard, replace only with same type and same rating of fuse.

Checking points after use of product

A) Make sure to clean the product so that use Deactivate the product and turn the power off in order.

B) Do not pull the power cord forcibly.

C) Comply with followings to keep the product properly.

Avoid places that can wet the product.

Avoid places where air pressure, temperature and humidity drastically change and where there are direct ray of sun, dirt, salt and sulfur.

Do not lean, shake or rock the product.

D) Clean accessories after use.

E) Make sure to clean the product so that users can use it immediately

If the product is out of order, do not try to repair it for yourself.

Do not modify use the product. If any modification is desired, ask OsteoSys or its authorized dealer for this service.

Check, maintenance and repair

Cautions in times of transportation of cart

If you have to move the cart on incline floor, you should detach the product from the cart so that the product does not slip to the ground.

Environmental protection

If the products are at the end of their useful lives, do not dispose them at your option. Contact OsteoSys or its authorized dealer for this service.

Others

Read the user's instructions carefully and use the product properly.

Chapter 5. Specifications & Software Updates

5.1 Specifications

5.2 Software Updates

5.1 Specifications

***General**

Classification	Class , Type B Applied part

***Device**

Dimensions	497mm x 279mm x 210mm
Weight	7.9 Kg
Input Voltage	AC 100V ~ 240V, Free Voltage (Single Phase)
Frequency	50/60Hz
Power	150W max.

***Transducer & Balloon**

Center Frequency	0.5MHz ± 10%
Ultrasound Output	4uW/cm^2
Bandwidth	> 30%
Diameter	31.75mm
Focus Type	Flat
Connector Type	UHF

***Measuring Circuit**

Input Analogue signal	Ultrasound Transducer, 2 channel, Bandwidth : 0.3 ~ 1MHz
Output Analogue signal	Amplitude : 200Vp-p, Pulse width : 4 usec
A/D Converting	8 bit, 32MHz
Measurement of Electric signal	The number of Data : 1024

***Environmental**

Operating Temperature	10 ~ 40
Transport / Storage Temperature	-10 ~ 70
Operating Humidity	30 ~ 75% relative humidity
Transport / Storage Humidity	0 ~ 90% relative humidity, non-condensing
Atmosphere	700 ~ 1060 hPa
Shock	Not to exceed 2G in six millisecond
Dust, Fumes, Airborne debris	Install system in a clean, well-ventilated area. Excessive dust and other airborne debris contaminants can impair sensitive parts. We recommend instituting a "No Smoking" policy in system area.

5.2 Software Updates

1. Updates to SONOST-2000 software are available at our homepage (http://www.osteosys.com).

2. Updates to SONOST-2000 software are free, regardless of the product warranty.

3. Updates to SONOST-2000 software are irregular, we will inform you through your email whenever SONOST-2000 software needs to be updated.

4. For details, call the OsteoSys Co., Ltd Customer Service Department or your OsteoSys Co., Ltd distributor.

Chapter 6 . Product Warranty

● Scope and Period of Warranty

(1) OsteoSys Co., Ltd. guarantees all new product against faults in materials or workmanship for a period of one year from date of shipment to purchaser. OsteoSys Co., Ltd. will, as sole and exclusive remedy, at no charge, replace any such defective unit returned to its service designated warranty period.

(2) This warranty applies only to failures from operating the product under conditions for which it was designed. Warranted product is to be used only for the intended and labeled indications presented in the literature accompanying the product.

(3) OsteoSys Co., Ltd. will charge service fees in following cases.
- If the product is out of order after the warranty period expires.
- If the product is out of order due to natural disasters such as fire, flood, windstorm, hail, lightning and earthquake.
- If the product is out of order due to improper transportation after installation and careless use.
- If the product is out of order due to improper repair or renovation by someone other than service personnel of the company.

(6) Cosmetic defects or deterioration will not be refinished or replaced. The costs of replacement of fuses are not covered.

(7) OsteoSys Co., Ltd. will not be responsible for any loss, damage, or injury resulting from delay in rendering service under this warranty.

(8) OsteoSys Co., Ltd. will not be responsible to you for incidental or consequential damages of any kind arising from or connected with the use of its equipment.

● What Should be Noted in times of Request of repair

(1) If the product is out of order, stop using it and read the manual carefully.

(2) Before you request for repair, switch off the product and contact a designated service agency after checking the name of model, serial number and date of purchase. OsteoSys Co., Ltd. will replace the defective product at no cost to you. OsteoSys Co., Ltd. will pay the shipping and insurance costs of product sent to you.

(3) Defective equipment shipped from you to OsteoSys Co., Ltd. must be packed in the replacement cartons. Shipping and insurance costs for the return of the defective product must be pre-paid by you.

(4) If you request the product information to repair the defective product yourself, we provide you with the proper information.

● This limited is in lieu of all other warranties expressed or implied, including warranties of merchant ability or fitness for any particular use. No representative or other person is authorized to represent or assume for OsteoSys Co., Ltd. any warranty liability beyond that set forth herein.